EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

L.W. et al., *by and through her parents and next friends, Samantha Williams and Brian Williams,*	)	
Plaintiffs,	)	No. 3:23-cv-00376 JUDGE RICHARDSON
v.	)	
JONATHAN SKRMETTI et al.,	)	
Defendants.	)	

EXPERT DECLARATION OF STEPHEN B. LEVINE, M.D.

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I. CREDENTIALS

1. I am Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine and maintain an active private clinical practice. I received my M.D. from Case Western Reserve University in 1967 and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, became a Full Professor in 1985, and in 2021 was honored to be inducted into the Department of Psychiatry's "Hall of Fame."

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' sexuality and sexual relations, therapies for sexual problems, and the relationship between love, intimate relationships, and wider mental health. In 2005, I received the Masters' and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association.

3. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010), and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five previously solo-authored books for professionals, I have published *Psychotherapeutic Approaches to Sexual Problems* (2020). The book has a chapter titled "The Gender Revolution."

4. In total I have authored or co-authored over 180 journal articles and book chapters, 27 of which deal with the issue of gender dysphoria. I was an invited member of a Cochrane Collaboration subcommittee that sought to publish a review of the scientific literature on the effectiveness of puberty blocking hormones and of cross-sex hormones for gender dysphoria for adolescents. Cochrane Reviews are a well-respected cornerstone of evidence-

based practice, comprising a systematic review that aims to identify, appraise, and synthesize all the empirical evidence that meets pre-specified eligibility criteria in response to a particular research question.

5. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

6. In the course of my five decades of practice treating patients who suffered from gender dysphoria, I have at one time or another recommended or supported social transition, cross-sex hormones, and surgery for particular patients, but only after extensive diagnostic and psychotherapeutic work.

7. In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. In that litigation, the U.S. Court of Appeals for the First Circuit in a 2014 (En Banc) opinion cited and relied on my expert testimony. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.

8. In 2019, I was qualified as an expert and testified concerning the diagnosis,

understanding, developmental paths and outcomes, and therapeutic treatment of transgenderism and gender dysphoria, particularly as it relates to children, in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District, Dallas County, TX (the "*Younger* litigation").

9. In 2019, I provided written expert testimony in the landmark case in the United Kingdom in the case of *Bell v. The Tavistock and Portman NHS Foundation Trust*. I have provided expert testimony in other litigation as listed in my curriculum vitae, which is attached as Exhibit "A".

10. I am regularly requested to speak on the topic of gender dysphoria and have given countless presentations to academic conferences and Departments of Psychiatry around the country. In May 2022, I organized and co-presented a symposium on the management of adolescent-onset transgender identity at American Psychiatric Association's Annual Meeting.

11. A fuller review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit "A".

12. The bases for my opinions expressed in this report are my professional experience as a psychiatrist, my knowledge of the pertinent scientific literature, and my review of the complaints filed by the plaintiffs and the United States and the expert declarations of Armand H. Matheny Antommaria, M.D., Ph.D, FAAP, HEC-C, Jack Turban, M.D., Aron Janssen, M.D., and Deanna Adkins, M.D.

13. I am being compensated for my time spent in connection with this case at a rate of $400.00 per hour. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

II. SUMMARY

14. A summary of the key points that I explain in this report is as follows:

a. Sex as defined by biology and reproductive function is clear, binary, and cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section III.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset, biological sex, mental health, intelligence, motivations for gender transition, socioeconomic status, country of origin, etc. Data from one population (e.g., adults) cannot be assumed to be applicable to others (e.g., children). (Section III.B.)

c. Among practitioners in the field, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria in children and adolescents. There are no generally accepted "standards of care," and existing studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals. The scientific basis for affirmative care is uncertain. (Section III.)

d. Transgender identity is not biologically based; it is not determined prenatally. Rather, gender dysphoria is a psychiatric condition that cannot be identified by any biological test or measurement. (Sections V.A, IV.B.)

e. Disorders of sexual development ("DSDs") are biologically-based

phenomena. It is an error to conflate and/or scientifically link DSDs with incidents of gender dysphoria. (Sections V.C, V.D.)

f. The large majority of children who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. Desistance is also increasingly observed among teens and young adults who have experienced "rapid onset gender dysphoria" — first manifesting gender dysphoria during or shortly after adolescence. (Section VI.A., VI.B.)

g. "Social transition" —the active affirmation of transgender identity—in young children is a powerful social intervention that will substantially reduce the number of children "desisting" from transgender identity. Therefore, the profound implications of "affirmative" treatment—which include taking puberty blockers and cross-sex hormones—must be taken into account where social transition is being considered. (Section VII.A,, VII.B.)

h. Administration of puberty blockers is not a benign "pause" of puberty, but rather a powerful medical and psychotherapeutic intervention that almost invariably leads to persistence in a transgender identity and, ultimately, to the administration of cross-sex hormones. (Section VII.C.)

i. The knowledge base concerning the "affirmative" treatment of gender dysphoria available today has very low scientific quality with many relevant long-term implications remaining unknown. (Section VIII.A.)

j. There are no studies that show that affirmation of transgender identity in young children reduces suicide or suicidal ideation, or improves long-term outcomes, as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much higher rates of suicidal ideation,

completed suicide, and negative physical and mental health conditions than does the general population. This is true before and after transition, hormones, and surgery. (Section VIII.B., VIII.C.)

k. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is scientifically baseless, and therefore unethical, to assert that a child or adolescent who express an interest in a transgender identity will kill him- or herself unless adults and peers affirm that child in a transgender identity. (Section IX.)

l. Hormonal interventions to treat gender dysphoria are experimental in nature and have not been shown to be safe, but rather put an individual at risk of a wide range of long-term and even life-long harms including: physical health risks; sterilization and the associated emotional response; impaired sexual response; surgical complications and life-long after-care; alienation of family and romantic relationships; elevated mental health risks of depression, anxiety, and substance abuse. (Section X.)

III. BACKGROUND ON THE FIELD

A. The biological baseline of the binary sexes

15. Biological sex is very well defined in all biological sciences including medicine. It is pervasively important in human development throughout the lifecycle.

16. Sex is not "assigned at birth" by humans visualizing the genitals of a newborn; it is not imprecise. Rather, it is clear, binary, and determined at conception. The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. As physicians know, sex determination occurs at the instant of conception, depending on whether a

sperm's X or Y chromosome fertilizes the egg. A publication of the federal government's National Institute of Health accurately summarizes the scientific facts:

> "Sex is a biological classification, encoded in our DNA. Males have XY chromosomes, and females have XX chromosomes. Sex makes us male or female. Every cell in your body has a sex— making up tissues and organs, like your skin, brain, heart, and stomach. Each cell is either male or female depending on whether you are a man or a woman." (NIH, How Sex and Gender Influence Health and Disease, 2022.)

17. The binary of biological sex is so fundamental and wide-ranging in its effects on human (and mammal) development and physiology that since 2014, the NIH has required all funded research on humans or vertebrate animals to include "sex as a biological variable" and give "adequate consideration of both sexes in experiments." (NIH 2015.) In 2021, the Endocrine Society issued a position paper elaborating on the application of the NIH requirement. The Endocrine Society correctly stated that "Sex is a biological concept . . . all mammals have 2 distinct sexes;" that "biological sex is . . . a fundamental source of intraspecific variation in anatomy and physiology;" and that "In mammals, numerous sexual traits (gonads, genitalia, etc.) that typically differ in males and females are tightly linked to each other because one characteristic leads to sex differences in other traits." (Bhargava et al. 2021 at 221, 229.)

18. The Endocrine Society emphasized that "The terms sex and gender should not be used interchangeably," and noted that even in the case of those "rare" individuals who suffer from some defect such that they "possess a combination of male- and female-typical characteristics, those clusters of traits are sufficient to classify most individuals as either biologically male or female." They concluded, "Sex is an essential part of vertebrate biology, but gender is a human phenomenon. Sex often influences gender, but gender cannot influence sex." (Bhargava et al. 2021 at 220-221, 228.)

19. As these statements and the NIH requirement suggest, biological sex pervasively

influences human anatomy, its development and physiology. This includes, of course, the development of the human brain, in which many sexually dimorphic characteristics have now been identified. In particular, the Endocrine Society and countless other researchers have determined that human brains undergo particular sex-specific developmental stages during puberty. This predictable developmental process is a genetically controlled coordinated endocrine response that begins with pituitary influences leading to increases in circulating sex hormones. (Bhargava et al. 2021 at 225, 229; Blakemore et al. 2010 at 926-927, 929; NIH 2001.)

20. Humans have viewed themselves in terms of binary sexes since the earliest historical records. Recognizing a concept of "gender identity" as something distinct from sex is a rather recent innovation whose earliest manifestations likely began in the late 1940s. Its usage became common in medicine in the 1980s and subsequently in the larger culture. Definitions of gender have been evolving and remain individual-centric and subjective. In a statement on "Gender and Health," the World Health Organization defines "gender" as "the characteristics of women, men, girls and boys that are socially constructed" and that "var[y] from society to society and can change over time," and "gender identity" as referring to "a person's deeply felt, internal and individual experience of gender." (WHO Gender and Health.) As these definitions indicate, a person's "felt" "experience of gender" is inextricably bound up with and affected by societal gender roles and stereotypes—or, more precisely, by the affected individual's *perception* of societal gender roles and stereotypes and their personal idiosyncratic meanings. Typically, gendered persons also have subtly different, often idiosyncratic, reactions to societal gender roles and stereotypes without preoccupation with changing their anatomy.

21. Thus, the self-perceived gender of a child begins to develop along with the early stages of identity formation generally, influenced in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when

a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child's sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Is it a product of the quality of early life caregiver attachments? Does it stem from trauma-based rejection of maleness or femaleness, and if so, flowing from what trauma? Does it derive from a tense, chaotic interpersonal parental relationship without physical or sexual abuse? Is it a symptom of another, as of yet, unrevealed, emotional disturbance or neuropsychiatric condition (autism)? The answers to these relevant questions are not scientifically known but are not likely to be the same for every trans-identified child, adolescent, or adult.

22. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape, musculature, internal organ size, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation and ejaculation. These are genetically programmed biological consequences of sex—the actual meaning of sex over time. Among the consequences of sex is the evolution and consolidation of gender identity during childhood, adolescence, and adulthood.

23. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes

testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not biologically attainable. (Levine 2018 at 6; Levine 2016 at 238.) It is possible for some adolescents and adults to pass unnoticed—that is, to be perceived by most individuals as a member of the gender that they aspire to be—but with limitations, costs, and risks, as I detail later.

B. Definition and diagnosis of gender dysphoria

24. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's genetically determined sex and the gender with which they identify or to which they aspire. The American Psychiatric Association first used the term "gender identity disorder" in its *Diagnostic and Statistical Manual of Mental Disorders* in 1980 (DSM-III). The term "gender dysphoria" was introduced in the 2013 version of the DSM (DSM-5). Today's version of the DSM ("DSM-5-TR") defines gender dysphoria with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

25. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after defining oneself as gay for several or more years and participating in a homosexual lifestyle; adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. (Levine 2021.)

26. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (Zucker 2018 at 10.) The

developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another.

27. The criteria used in DSM-5-TR to identify Gender Dysphoria include a number of signs of discomfort with one's natal sex and vary somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in . . . important areas of functioning" such as social, school, or occupational settings. The symptoms must persist for at least six months.

28. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that reflect constrictive notions of what men and women can be. (Levine 2017 at 7.) A young child's—or even an adolescent's—understanding of this topic is quite limited. Nor can they grasp what it may mean for their future to be sterile. (Levine et al, 2022.) These children and adolescents consider themselves to be relatively unique; they do not realize that discomfort with the body and perceived social role is neither rare nor new to civilization. What is new is that such discomfort is thought to indicate that they must be a trans person.

C. Impact of gender dysphoria on minority and vulnerable groups

29. Given that, as I discuss later, a diagnosis of gender dysphoria is now frequently putting even young children on a pathway that leads to irreversible physical changes and sterilization by young adulthood, it should be of serious concern to all practitioners that minority and vulnerable groups are receiving this diagnosis at disproportionately high rates. These include: children of color (Rider et al. 2018), children with mental developmental disabilities (Reisner et

al. 2015), children on the autistic spectrum (at a rate more than 7x the general population) (Shumer et al. 2016; van der Miesen et al. 2018), children with ADHD (Becerra- Culqui et al. 2018), children residing in foster care homes, adopted children (at a rate more than 3x the general population) (Shumer et al. 2017), victims of childhood sexual or physical abuse or other "adverse childhood events" (Thoma 2021 et al.; Newcomb et al. 2020; Kozlowska et al.,2021), children with a prior history of psychiatric illness (Edwards-Leeper et al. 2017; Kaltiala- Heino et al. 2015; Littman 2018), and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys) (Rider et al. 2018 at 4).

D. Three competing conceptual models of gender dysphoria and transgender identity

30. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the distinctions.

31. Gender dysphoria is **conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering**, comparable to diseases that are curable before it spreads, such as melanoma or sepsis. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.

32. Gender dysphoria is a psychiatric, not a medical, diagnosis. Since its inception in

DSM-III in 1980, it has always been specified in the psychiatric DSM manuals and has not been specified in medical diagnostic manuals. Notably, gender dysphoria is the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine 2016 at 240.)

33. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that may have been first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine 2016 at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self or a sense of self impaired by later adversity or abuse. The purpose is to ameliorate suffering when the underlying problem cannot be solved. MHPs first work with the patient and (ideally) family to learn about the events and processes that may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play and adolescents work out their issues by adopting various interests and identity labels.

34. There is evidence among adolescents that peer social influences through "friend groups" (Littman 2018) or through the internet can increase the incidence of gender dysphoria or claims of transgender identity. Responsible MHPs will want to probe these potential influences to better understand what is truly deeply tied to the psychology of the patient, and what may instead be being "tried on" by the youth as part of the adolescent process of self-exploration and self-definition. The dramatic recent increase in adolescents who do not identify as heterosexual is evidence of social influences in today's cultural environment.

35. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve—often markedly—across the individual's lifetime. This includes gender. Some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner. As I review later, however, this assertion is not supported by science.[1]

36. The third paradigm through which gender dysphoria is alternatively conceptualized is from **a sexual minority rights perspective**. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, and many mental health professionals. Obviously, however, this is not a medical or psychiatric perspective. Unfortunately, it appears to be the most powerful perspective that exists in the public, non-scientific debate.

E. Four competing models of therapy

37. Few would disagree that the human psyche is complex. Few would disagree that children's and adolescents' developmental pathways typically have surprising twists and turns. The complexity and unpredictability of childhood and adolescent development equally applies to trans-identifying youth. Because of past difficulties of running placebo-controlled clinical trials in the transgender treatment arena, substantial disagreements among professionals about the causes of trans identities and their ideal treatments exist. These current disagreements might have been minimized if trans treated persons were carefully followed up to determine long term

[1] Even the advocacy organization The Human Rights Campaign asserts that a person can have "a fluid or unfixed gender identity." https://www.hrc.org/resources/glossary-of-terms.

outcomes. They have not been. When we add this to the very different current paradigms for understanding transgender phenomena, it is not scientifically surprising that disagreements are sharply drawn. It is with this in mind that I summarize below the leading approaches, and offer certain observations and opinions concerning them.

(1) The "watchful waiting" therapy model

38. In Section V.A below I review the uniform finding of eleven follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated by social transition approaches.

39. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach seeks to allow for the fluid nature of gender identity in children to naturally evolve—that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. Treating any other psychological co-morbidities—that is, other mental illnesses as defined by DSM-5-TR (separation anxiety disorder, attention deficit hyperactivity disorder, autism spectrum disorder, obsessive compulsive disorder, etc), or subthreshold for diagnosis but behavioral problems that the child may exhibit (school avoidance, bedwetting, inability to make friends, aggression/defiance) without a focus on gender (**model #1**); and

b. No treatment at all for anything but a regular follow-up appointment. This might be labeled a "hands off" approach **(model #2**).

(2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)

40. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes

as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

41. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine 2017 at 8; Spiliatis 2019; Levine 2021.Levine et al, 2022) I and others have reported success in alleviating distress in this way for at least some patients, whether the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared or not. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

42. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient to appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" to be kind, compassionate, caring, noncompetitive, to love the arts, and to be devoted to others' feelings and needs. (Levine 2017 at 7.) Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture, and to be aggressive. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

43. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a

manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. They may enable the patient to understand the commonality of discomfort with the body's physiology, the growth process, and the struggle to accept oneself during the pubertal developmental process. Patients need to understand that this discomfort with one's body, per se, and one's attractiveness relative to others, typically lasts for several or more years. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

44. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

45. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine 2019.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. There are now a series of articles and at least one major book on the

psychological treatment of adolescents. (D'Angelo et al. 2021 at 7-16; Evans & Evans 2021.) Among detransitioners, a large percentage express regret that their affirmative therapists did not recommend psychotherapy before encouraging hormonal treatment (*Littman, (2021). Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: A survey of 100 detransitioners. Archives of Sexual Behavior, 50(8)3353-3369). Exposito-Campos pointed out the large amount reports on detransition and the far greater traffic on various nonprofessional websites (Exposito-Campos, 2021).*

(3) The affirmation therapy model (model #4)

46. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc., associated with transgender identity. They argue that the child should be comprehensively re-socialized in grade school or junior or senior high school in their aspired-to gender. As I understand it, this is asserted as a reason why male students who assert a female gender identity must be permitted to compete in girls' or women's athletic events. These advocates treat any question about the causes of the child's transgender identification as inappropriate. They may not recognize the child's ambivalence. They assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

47. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. This claim is simply not supported by the clinical data we have available to us. Indeed, available long-term data contradicts this claim. I address physical

and mental health outcomes in Section VII below, and suicide in Section VIII below.

48. The commonly referenced scientific basis for affirmative care of both early life onset and adolescent onset gender dysphoria are two reports from deVries et al (2011, 2014) that seemingly demonstrated the resolution of gender dysphoria after a sequence of puberty blocking hormones, cross-sex hormones, and breast removal or vaginoplasty. However, recently three articles describing the distinct limitations of the "Dutch Protocol" have been widely circulating throughout the world. (Levine et al, 2022; Biggs, 2022, Abbruzzese et al, 2023). It is now apparent that the basis for such affirmative care is not scientifically solid. Rapid diffusion of the innovative Dutch Protocol occurred without the scientifically required confirmatory more rigorous studies. The one attempt to repeat their protocol in the UK failed to demonstrate psychological benefits claimed by the Dutch studies. (Carmichael et al 2021).

49. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics and is not supported by science. Instead of science, this approach is currently being reinforced by an echo-chamber of approval from other like-minded child-oriented professionals who do not sufficiently consider the known negative medical and psychiatric outcomes of trans adults. Rather than recommend social transition in grade school, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents, and the MHP and the child, are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with by each of them.

50. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics. This, however, requires time and effort and for

many parents, a challenge to find a therapist to do such work with them.

IV. THERE IS NO CONSENSUS OR AGREED "STANDARD OF CARE" CONCERNING THERAPEUTIC APPROACHES TO CHILD OR ADOLESCENT GENDER DYSPHORIA.

51. There is far too little firm clinical evidence in this field to permit any evidence-based standard of care. Given the lack of scientific evidence, it is neither surprising nor improper that—as I detailed in Section II—there is a diversity of views among practitioners as to the best therapeutic response for the child, adolescent, or young adult who suffers from gender dysphoria.

52. Reviewing the state of opinion and practice in 2021, the Royal Australian and New Zealand College of Psychiatrists observed that "There are polarised views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people." (RANZCP, 2021.) Similarly, a few years earlier prominent Dutch researchers noted: "[T]here is currently no general consensus about the best approach to dealing with the (uncertain) future development of children with GD, and making decisions that may influence the function and/or development of the child — such as social transition." (Ristori & Steensma 2016 at 18.)[2] In this Section, I comment on some of the more important areas of disagreement within the field.

A. Experts and organizations disagree as to whether "distress" is a necessary element for diagnoses that justifies treatment for gender identity issues.

53. As outlined in Section II.B above, "clinically significant distress" is one of the criteria used in DSM-5 to identify gender dysphoria. This indicates a heightened level of distress that rises beyond a threshold level of social awkwardness or discomfort with the changing body. It is known that many trans-identified youth with incongruence between their sexed bodies and

[2] *See also* Zucker 2020 which questions the merit of social transition as a first-line treatment.

their gender identity choose not to take hormones; their incongruence is quite tolerable as they further clarify their three elements of sexual identity—gender identity, orientation, and intention (what the person wants to do with a partners body during sex and what that person wants to do to their own body to be aroused). This population raises the questions of what distress is being measured when DSM-5-TR criteria are met and what else might be done about it. However, there is no "clinically significant distress" requirement in World Health Organization's International Classification of Diseases (ICD-11) criteria for gender incongruence, which rather indicates "a marked and persistent incongruence between an individual's experienced gender and the assigned sex." (World Health Organization 2019.)

54. Therefore, even between these two committee-based authorities, there is a significant disagreement as to what constitutes a gender condition justifying life-changing interventions. To my knowledge, some American gender clinics and practitioners are essentially operating under the ICD-11 criteria rather than the DSM-5-TR criteria, prescribing transition for children, hormonal interventions for slightly older children, and different hormones for adolescents who assert a desire for a transgender identity whether or not they are exhibiting "clinically significant distress." Others adhere to the DSM-5 diagnostic standard.

55. It is ironic that affirmative care is said by advocates to be life enhancing and often to be lifesaving because of the risk of suicide. Based on the DSM-5-TR criterion, distress is required for the diagnosis and its subsequent hormonal and surgical treatments. Gender incongruence is often referred to as a unique form of suffering. Yet, ICD-11 the criteria for the diagnosis of Gender Incongruence do not require distress, just the wish to have the characteristics of the other sex and to change their own sex demarcating features. It seems that as the field moves on in time, the emphasis is on desire rather than distress, pain, or suffering. The intense suffering required for the diagnosis of this former "medical disorder" has now become "this is

not a disorder at all, and people should be given what they desire, whether or not they are distressed or whether their functioning is impaired."

56. I will add that even from within one "school of thought," it is not responsible to make a single, categorical statement about the proper treatment of children or adolescents presenting with gender dysphoria or other gender-related issues. There is no single pathway to the development of a trans identity and no reasonably uniform short- or long-term outcome of medically treating it. As individuals grow physically, mature psychologically, and experience or fail to experience satisfying romantic relationships, their life course depends on their differing psychological, social, familial, and life experiences. There should be no trust in assertions that trans identified youth must be treated in a particular manner to avoid harm for two reasons. First, there is no systematic data on the nature of, and the rate of harms of either affirmative treatment, no treatment, or psychological only treatment. Second, as in other youthful psychiatric and other challenges, outcomes vary. There is no psychiatric condition—depression, anxiety, schizophrenia—where one size fits all.

B. Opinions and practices vary widely about the utilization of social transition for children and adolescents.

57. The World Professional Association for Transgender Health (WPATH) has published a guidance document under the title "Standards of Care." Below, I will provide some explanation of WPATH and its "Standards of Care," which are not the product of a strictly scientific organization, and they are by no means accepted by all or even most practitioners as setting out best practices.

58. Here, however, I will note that WPATH does not take a position concerning whether or when social transition may be appropriate for pre-pubertal children. Instead, the WPATH "Standards of Care version 7" states that the question of social transition for children is a "controversial issue" and calls for mental health professionals to support families in what it

describes as "difficult decisions" concerning social transition. Its version 8, however, no longer uses the word "controversial" even though it extensively discusses the dangers of harms versus the possibility of benefits of early transition (Coleman et al, 2022.)

59. Dr. Erica Anderson is a prominent practitioner in this area who identifies as a transgender woman, who was the first transgender president of USPATH, and who is a former board member of WPATH. Dr. Anderson recently resigned from those organizations and has condemned automatic approval of transition upon the request of a child or adolescent, noting that "adolescents . . . are notoriously susceptible to peer influence," that transition "doesn't cure depression, doesn't cure anxiety disorders, doesn't cure autism-spectrum disorder, doesn't cure ADHD," and instead that "a comprehensive biopsychosocial evaluation" should proceed allowing a child to transition. (Davis 2022.) And as I have explained previously, my own view based on 50 years of experience in this area favors strong caution before approving life-altering interventions such as social transition, puberty blockers, or cross-sex hormones.

C. The WPATH "Standards of Care" is not an impartial or evidence-based document.

60. Because WPATH is frequently cited by advocates of social, hormonal, and surgical transition, I provide some context concerning that private organization and its "Standards of Care." WPATH insists its guidance is evidence-based. But its reviews of the evidence strikingly omit evidence to the contrary. This renders it unbalanced or biased and not in keeping with the traditions of respected clinical science.

61. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and

its recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Harry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health (WPATH).

62. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization. Its associate members are not health care professionals. The later have various medical specialties, various mental health degrees, and varying experience and approaches to caring for these patients.

63. WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine 2016 at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs. Such views have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with "There are none. This is how it is done." Such a response does not accurately reflect what is known, what is unknown, and the diversity of clinical approaches in this complex field.

64. The reviews of WPATH's 7th edition of standards of care published in 2021 by Dahlen et al and Sapir in 2022 have clarified the low quality, low reliability, and bias inherent in its

recommendations. (Dahlen et al 2022.) Its 8th edition, which is three times the length of the 7th, has not gained additional confidence in its scientific merit. The Standards of Care ("SOC") document is the product of an effort to be balanced, but it is not politically neutral. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. It articulates policy. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered. And, of course, once individuals have socially, medically, and surgically transitioned, WPATH members and the trans people themselves at the meetings are committed to supporting others in their transitions. Not only have some trans participants been distrustful or hostile to those who question the wisdom of these interventions, their presence makes it difficult for professionals to raise their concerns. Vocal trans rights advocates have a worrisome track record of attacking those who have alternative views. (Dreger 2015; McNamarra, et al 2022.)

65. In recent years, WPATH has fully adopted some mix of the medical and civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; but the pathway to the development of this state is not. (Levine 2016 at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance. In actual practice, that thoughtful person may be as young as age 11!

66. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists, psychologists, and pediatricians who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self-

selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism and therefore, deviates from the philosophical core of medical science. There are pediatricians, psychiatrists, endocrinologists, and surgeons who object strongly, on professional grounds, to transitioning children and providing affirmation in a transgender identity as the first treatment option. WPATH does not speak for all of the medical profession.

67. In 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be identified in the DSM as a pathology.[3] This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

68. In my experience some current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric co-morbidities. Further, being a mental health professional, per se, does not guarantee experience and skill in recognizing and effectively intervening in serious or subtle patterns. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical degrees. The 8th version of the SOC continues this tradition. When this document recommends a comprehensive

[3] WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

psychiatric evaluation, it fails to elaborate its duration, the topics to be covered, and necessary treatment results of the commonly found previous and co-current psychiatric conditions. It emphasizes the test the evaluation; it does not emphasize what to do with the identified problems, other than to state that they must be under reasonable control. Policy statements are one thing, but how those policies are implemented is another.

D. Opinions and practices differ widely with respect to the proper role of psychological counseling before, as part of, or after a diagnosis of gender dysphoria.

69. In Version 7 of its Standards of Care, released in 2012, WPATH downgraded the role of counseling or psychotherapy, and the organization no longer sees psychotherapy without transition and hormonal interventions as a potential path to eliminate gender dysphoria by enabling a patient to return to or achieve comfort with the gender identity aligned with his or her biology. Around the world, many prominent voices and practitioners disagree. For example, renowned gender therapists Dr. Laura Edwards-Leeper and Dr. Erica Anderson (who, as mentioned above, identifies as a transgender woman) have recently spoken out arguing that children and adolescents are being subjected to puberty blockers and hormonal intervention far too quickly, when careful and extended psychotherapy and investigation for potential causes of feelings of dysphoria (such as prior sexual abuse) should be the first port of call and might resolve the dysphoria. (Edwards-Leeper & Anderson 2021; Davis 2022.)

70. In a recently published position statement on gender dysphoria, the Royal Australian and New Zealand College of Psychiatrists emphasized the critical nature of mental health treatment for gender dysphoric minors, stressing "the importance of the psychiatrist's role to undertake thorough assessment and evidence-based treatment ideally as part of a multidisciplinary team, especially highlighting co-existing issues which may need addressing and treating." The Royal College also emphasized the importance of assessing the "psychological

state and context in which Gender Dysphoria has arisen," before any treatment decisions are made. (RANZCP, 2021.)

71. Dr. Paul Hruz of the University of Washington St. Louis Medical School has noted, "The WPATH has rejected psychological counseling as a viable means to address sex–gender discordance with the claim that this approach has been proven to be unsuccessful and is harmful. (Coleman et al. 2012.) Yet the evidence cited to support this assertion, mostly from case reports published over forty years ago, includes data showing patients who benefited from this approach (Cohen-Kettenis and Kuiper 1984)." (Hruz 2020.)

72. In several recent publications, my colleagues and I have demonstrated that both the Endocrine Society's and WPATH's citations for the scientific basis of affirmative care of adolescents reference the same two Dutch studies. We have demonstrated in considerable detail the limitations of these studies, their lack of applicability to today's transgendered youth, and the dangers of following therapeutic fashion rather than evidence-based medicine. (Levine et al, 2022; Abbruzzese et al, 2023.)

E. Opinions and practices vary widely with respect to the administration of puberty blockers and cross-sex hormones.

73. There is likewise no broadly accepted standard of care with respect to use of puberty blockers. The WPATH Standards of Care explicitly recognize the lack of any consensus on this important point, stating: "Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. . . The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings."

74. The use of puberty blockers as a therapeutic intervention for gender dysphoria is often justified by reference to the seminal work of a respected Dutch research team that developed a protocol that administered puberty blockers to children no younger than age 14. However, it is well known that many clinics in North America now administer puberty blockers to children at much younger ages than the "Dutch Protocol" allows. (Zucker 2019.) The Dutch protocol only treated children with these characteristics: a stable cross gender identity from early childhood; dysphoria that worsened with the onset of puberty; were otherwise psychologically healthy; had healthy families; the patient and family agreed to individual and family counselling throughout the protocol. But the experience and results of the Dutch model is being used as a justification for giving puberty blockers to children who differ considerably from these criteria. Its authors have also recently noted this fact (de Vries 2020).

75. However, Zucker notes that "it is well known" that clinicians are administering cross-sex hormones, and approving surgery, at ages lower than the minimum age thresholds set by that "Dutch Protocol." (Zucker 2019 at 5.)

76. Similarly, at least one prominent clinic—that of Dr. Safer at Columbia's Mt. Sinai Medical Center—is quite openly admitting patients even for *surgical* transition who are not eligible under the criteria set out in WPATH's Standards of Care. A recent study published by Dr. Safer and colleagues revealed that of a sample of 139 individuals, 45% were eligible for surgery "immediately" under the center's own criteria, while only 15% were eligible under WPATH's criteria. That is, *three times* as many patients immediately qualified for surgery under the center's loose standards than would have qualified under WPATH criteria. (Lichenstein et al. 2020.)

77. Internationally, there has been a recent marked trend *against* use of puberty blockers, as a result of extensive evidence reviews by national medical bodies, which I discuss later. The main gender clinic in Sweden has declared that it will no longer authorize use of puberty blockers for

minors below the age of 16. Finland has similarly reversed its course, issuing new guidelines that allow puberty blockers only on a case-by-case basis after an extensive psychiatric assessment. A landmark legal challenge against the UK's National Health Service in 2020 by "detransitioner" Keira Bell led to the suspension of the use of puberty blockers and new procedures to ensure better psychological care, as well as prompting a thorough evidence review by the National Institute for Health and Care Excellence (NICE 2021a; NICE 2021b).[4] That review in 2022 reorganized trans adolescent care throughout the UK and emphasized the need to focus on the patients' psychological state rather than treat first the gender incongruence. Puberty blockers are not to be initially employed.

78. In this country, some voices in the field are now publicly arguing that *no* comprehensive mental health assessment at all should be required before putting teens on puberty blockers or cross-sex hormones (Ghorayshi 2022), while Dr. Anderson and Dr. Edwards-Leeper argue that U.S. practitioners are already moving too quickly to hormonal interventions. (Edwards-Leeper & Anderson 2021; Davis 2022.) It is evident that opinions and practices are all over the map.

79. In 2018, committee of the American Academy of Pediatricians issued a policy statement supporting administration of puberty blockers to children diagnosed with gender dysphoria. No other American medical association has endorsed the use of puberty blockers. Pediatricians are neither endocrinologists nor psychiatrists. Many pediatricians were horrified by the recommendation. Dr. James Cantor published a peer-reviewed paper detailing that the Academy's statement was not evidence-based and misdescribed the few scientific sources it did reference. (Cantor 2019.) It has been well noted in the field that the AAP has declined invitations to publish any rebuttal to Dr. Cantor's analysis. But this is all part of ongoing debate, simply

[4] The decision requiring court approval for administration of hormones to any person younger than age 16 was later reversed on procedural grounds by the Court of Appeal and is currently under consideration by the UK Supreme Court.

highlighting the absence of any generally agreed standard of care. In 2022, the same committee of the AAP modified their recommendation supporting alternative treatments but still held out that affirmative care is still a viable option. Evidence after all is required for policy decisions and the 2018 evidence base is now widely appreciated as insubstantial. Nonetheless, the 2018 policy, now softened considerably, is what is quoted as "social transition is supported by the American Academy of Pediatrics." No mention is made of the many pediatricians who find this policy to be dangerous.

80. The 2017 Endocrine Society Guidelines themselves expressly state that they are *not* "standards of care." The document states: "The guidelines cannot guarantee any specific outcome, *nor do they establish a standard of care*. The guidelines are not intended to dictate the treatment of a particular patient." (Hembree et al. 2017 at 3895 (emphasis added).) Nor do the Guidelines claim to be the result of a rigorous scientific process. Rather, they expressly advise that their recommendations concerning use of puberty blockers are based only on "low quality" evidence.

81. The 2017 Guidelines assert that patients with gender dysphoria often must be treated with "a safe and effective hormone regimen. . ." Notably, however, the Guidelines do not make any firm statement that use of puberty blockers for this purpose *is* safe, and the Guidelines go no further than "suggest[ing]" use of puberty blockers—language the Guidelines warn represents only a "weak recommendation." (Hembree 2017 at 3872.) Several authors have pointed out that not only were the Endocrine Society suggestions regarding use of puberty blockers reached on the basis of "low quality" evidence, but its not-quite claims of 'safety' and 'efficacy' are starkly contradicted by several in-depth evidence reviews. (Laidlaw et al., 2019; Malone et al. 2021.) The most recent systematic independent reviews of hormonal treatment of adolescents reaffirmed the poor quality of

evidence making their use questionable (Brignardello-Peterson, & Wiercioch 2022; Ludviggsson et al, 2023). I detail these contradictory findings in more detail in Section VII below.

82. While there is too little meaningful clinical data and no consensus concerning best practices or a "standard of care" in this area, there are long-standing ethical principles that do or should bind all medical and mental health professionals as they work with, counsel, and prescribe for these individuals.

83. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, principles of medical ethics prohibit the treatment.

V. TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED.

84. There is no medical consensus that transgender identity has any biological basis. Furthermore, there is considerable well-documented evidence that is inconsistent with the hypothesis of a biological basis for gender identity—at least in the large majority of currently-presenting patients.

A. No theory of biological basis has been scientifically validated.

85. At the outset, the attempt to identify a single, biological cause for psychiatric conditions (including gender dysphoria) has been strongly criticized as "out of step with the rest of medicine" and as a lingering "ghost" of an understanding of the nature of psychiatric conditions that is now broadly disproven. (Kendler 2019 at 1088-1089.) Gender dysphoria is defined and diagnosed only as a psychiatric, not a medical, condition. Courts need to have clarified that just because some physicians use medication and surgery to treat gender dysphoria does not make it a

"medical condition" or that the psychological identity has been determined by a biological mechanism.

86. While some have pointed to very small brain scan studies as evidence of a biological basis, no studies of brain structure of individuals identifying as transgender have found any statistically significant correlation between any distinct structure or pattern and transgender identification, after controlling for sexual orientation and exposure to exogenous hormones. (Sarawat et al. 2015 at 202; Frigerio et al. 2021.)

87. Indeed, the Endocrine Society 2017 Guidelines recognizes: "With current knowledge, we cannot predict the psychosexual outcome for any specific child," and "there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty." (Hembree et al. 2017 at 3876.)

88. In short, no biological test or measurement has been identified that provides any ability to predict which children will exhibit, and which children will persist in, gender dysphoria or a transgender identification. Unless and until such a test is identified, the theory of a biological basis is a hypothesis still searching for support. A hypothesis is not a fact, and responsible scientists will not confuse the two. It should be noted that employing the belief in biological determinism of gender dysphoria eases a doctor's ethical qualms about changing the body to fit the current state of a patient's mind. These doctors may consider themselves fixing a mistake of nature as they would when repairing a cleft palate or providing cortisone to a child whose adrenal glands' function is insufficient.

B. Large changes across time and geography in the epidemiology of transgender identification are inconsistent with the hypothesis of a biological basis for transgender identity.

89. In fact, there is substantial evidence that the "biological basis" theory is incorrect,

at least with respect to the large majority of patients presenting with gender dysphoria today.

90. **Vast changes in incidence:** Historically, there were very low reported rates of gender dysphoria or transgender identification. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be at 2-14 per 100,000, or between 0.002% and 0.014%. (APA 2013 at 454.) Recently however, these numbers have increased dramatically, particularly in adolescent populations. Recent surveys estimate that between 2-9% of high school students self- identify as transgender or "gender non-conforming." with a significantly large increase in adolescents claiming "nonbinary" gender identity as well. (Johns et al. 2019; Kidd et al. 2021.) Consistent with these surveys, gender clinics around the world have seen numbers of referrals increase rapidly in the last decade, with the Tavistock clinic in London seeing a 30-fold increase in the last decade (GIDS 2019), and similar increases being observed in Finland (Kaltiala-Heino et al. 2018), the Netherlands (de Vries 2020), and Canada (Zucker 2019). The rapid change in the number of individuals experiencing gender dysphoria points to social and cultural, not biological, causes.

91. **Large change in sex ratio:** In recent years there has been a marked shift in the sex ratio of patients presenting with gender dysphoria or transgender identification. The Tavistock clinic in London saw a ratio of 4 biological females(F):5 biological males(M) shift to essentially 11F:4M in a decade. (GIDS 2019.) One researcher summarizing multiple sources documented a swing of 1F:2M or 1F:1.4M through 2005 to 2F:1M generally (but as high as 7F:1M) in more recent samples. (Zucker 2019 at 2.) This phenomenon has been noted by Dr. Erica Anderson, who said: "The data are very clear that adolescent girls are coming to gender clinics in greater proportion than adolescent boys. And this is a change in the last couple of years. And it's an open question: What do we make of that? We don't really know what's going on. And we should be concerned about it." (Davis 2022.) Again, this large and rapid change in who is experiencing gender dysphoria points to social, not biological, causes.

92. **Clustering**: Dr. Littman's recent study documented "clustering" of new presentations of gender dysphoria among natal females in specific schools and among specific friend groups. This again points strongly to social causes for gender dysphoria at least among the adolescent female population. (Littman 2018.)

93. **Desistance:** As I discuss later, there are very high levels of desistance among children diagnosed with gender dysphoria, as well as increasing (or at least increasingly vocal) numbers of individuals who first asserted a transgender identity during or after adolescence, underwent substantial medical interventions to "affirm" that trans-identity, and then "desisted" and reverted to a gender identity congruent with their sex. (See Section V.B below.) These narratives, too, point to a social and/or psychological cause, rather than a biological one.

94. **"Fluid" gender identification:** Advocates and some practitioners assert that gender identity is not binary but can span an almost endless range of gender identity self-labels, which a given individual may try on, inhabit, and often discard. (A recent article identifies 72.[5]) I have not heard any theory offered for how there is or could be a biological basis for gender identity as now expansively defined.

95. I frequently read attempts to explain away the points in this Section V. They include: these problems always existed, but children are now learning that there are effective treatments for their dilemma and are simply seeking them. And children have hidden their trans identity throughout childhood and now that trans people are recognized and accepted, they are presenting themselves. And now pediatricians realize that girls can have gender dysphoria and are referring them to gender clinics. But these are all mere hypotheses unsupported by concrete evidence. One set of unproven hypotheses cannot provide support for the unproven hypothesis of

[5] Allarakha, *What Are the 72 Other Genders?*, MedicineNet, available at: https://www.medicinenet.com/what_are_the_72_other_genders/article.html.

biological basis. And none of these hypotheses could even potentially explain the failure of science thus far to identify any predictive biological marker of transgender identification. There is much sociological evidence that in the last decade, increasing numbers of adolescents are identifying as something other than heterosexual. Biological phenomena do not evolve suddenly.

96. **Therapies affect gender identity outcomes:** Finally, the evidence shows that therapeutic choices can have a powerful effect on whether and how gender identity does change, or gender dysphoria desists. Social transition of juveniles, for instance, strongly influences gender identity outcomes to such an extent that it has been described a "unique predictor of persistence." (See Section VI.B below.) Again, this observation cuts against the hypothesis of biological origin.

C. Disorders of sexual development (or DSDs) and gender identity are very different phenomena, and it is an error to conflate the two.

97. Some have pointed to individuals who suffer from disorders of sexual development (DSDs) as evidence that sex is not binary or clearly defined, or as somehow supporting the idea that transgender identification has a biological basis. I have extensively detailed that sex is clear, binary, and determined at conception. (Section III.) Here I explain that gender dysphoria is an entirely different phenomenon than DSDs—which unlike transgender identity are indeed biological phenomena. It is an error to conflate the two distinct concepts.

98. Every DSD reflects a genetic enzymatic defect with negative anatomic and physiological consequences. As the Endocrine Society recognized in a 2021 statement: "Given the complexities of the biology of sexual determination and differentiation, it is not surprising that there are dozens of examples of variations or errors in these pathways associated with genetic mutations that are now well known to endocrinologists and geneticists; in medicine, these situations are generally termed *disorders of sexual development* (DSD) or *differences in*

sexual development." Gender Identity on the other hand is uniformly defined as a subjective "sense" of being, a feeling or state of mind. (Section II.C.)

99. The vast majority of those who experience gender dysphoria, or a transgender identity, do not suffer from any DSD, nor from any genetic enzymatic disorder at all. Conversely, many who suffer from a DSD do not experience a gender identity different from their chromosomal sex (although some may). In short, those who suffer from gender dysphoria are not a subset of those who suffer from a DSD, nor are those who suffer from a DSD a subset of those who suffer from gender dysphoria. The two are simply different phenomena, one physical with psychological effects, the other mental with physical effects only if treated medically or surgically. The issue here is not whether biological forces play a role in personality development; it is whether there is strong evidence that it is determinative. Science has come too far to revert to single explanations for gender dysphoria or any psychiatric diagnosis.

100. The importance of this distinction is evident from the scientific literature. For example, in a recent study of clinical outcomes for gender dysphoric patients, Tavistock Clinic researchers *excluded* from their analysis any patients who did not have "normal endocrine function and karyotype consistent with birth registered sex." (Carmichael et al. 2021 at 4.) In other words, the researchers specifically *excluded* from their study anyone who suffered from genetic-based DSD, or a DSD comprising any serious defect in hormonal use pathways, to ensure the study was focused only on individuals experiencing the psychological effects of what we might call "ordinary" gender dysphoria.

D. Studies of individuals born with DSDs suggest that there may be a biological predisposition towards *typical* gender identifications, but they provide no support for a biological basis for *trans*gender identification.

101. Studies of individuals born with serious DSDs have been pointed to as evidence of a biological basis for transgender identification. They provide no such support.

102. One well-known study by Meyer-Bahlburg reviewed the case histories of a number of XY (i.e. biologically male) individuals born with severe DSDs who were surgically "feminized" in infancy and raised as girls. (Meyer-Bahlburg 2005.) The majority of these individuals nevertheless later adopted male gender identity—suggesting a strong biological predisposition towards identification aligned with genetic sex, even in the face of feminized genitalia from earliest childhood, and parental "affirmation" in a transgender identity. But at the same time, the fact that some of these genetically male individuals did *not* later adopt male gender identity serves as evidence that medical and social influences can indeed encourage and sustain transgender identification.

103. Importantly, the Meyer-Bahlburg study did *not* include any individuals who were assigned a gender identity congruent with their genetic sex who subsequently adopted a *trans*gender identity. Therefore, the study can provide no evidence of any kind that supports the hypothesis of a biological basis for *trans*gender identity. A second study in this area (Reiner & Gearhart 2004) likewise considered exclusively XY subjects, and similarly provides evidence only for a biological bias towards a gender identity congruent with one's genetic sex, even in the face of medical and social "transition" interventions. None of this provides any evidence at all of a biological basis for transgender identity.

VI. GENDER IDENTITY IS EMPIRICALLY NOT FIXED FOR MANY INDIVIDUALS.

104. There is extensive evidence that gender identity changes over time for many individuals.[6] That evidence is summarized below.

A. Most children who experience gender dysphoria ultimately "desist" and resolve to cisgender identification.

[6] See n1 *supra*.

105. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition or puberty blocking hormone therapy, it does *not* persist through puberty.

106. A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria (11 studies) and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition." (Cantor 2019 at 1.) Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance . . . the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance." (Adelson et al. 2012 at 963; see also Cohen-Kettenis 2008 at 1895.) The Endocrine Society recognized this important baseline fact in its 2017 Guidelines. (Hembree 2017 at 3879.) It should be noted that the reason that the Dutch Protocol waited until age 14 to initiate puberty blockers was that it was well known that many children would desist if left free of hormonal intervention until that age.

107. Findings of high levels of desistance among children who experience gender dysphoria or incongruence have been reaffirmed in the face of critiques through thorough reanalysis of the underlying data. (Zucker 2018.)

108. As I explained in detail in Section V above, it is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist.

109. It does appear that prevailing circumstances during particularly formative years can have a significant impact on the outcome of a juvenile's gender dysphoria. A 2016 study reviewing the follow-up literature noted that "the period between 10 and 13 years" was "crucial" in that "both persisters and desisters stated that the changes in their social environment, the

anticipated and actual feminization or masculinization of their bodies, and the first experiences of falling in love and sexual attraction in this period, contributed to an increase (in the persisters) or decrease (in the desisters) of their gender related interests, behaviors, and feelings of gender discomfort." (Ristori & Steensma 2016 at 16.) In 2022, Olson et al. published data about the very low rates of desistence five years after social transition of children between ages of 3 and 12 (Olsen et al, 2022.) As I discuss again in Section VII below, there is considerable evidence that early transition and affirmation causes far more children to persist in a transgender identity.

B. Desistance is increasingly observed among teens and young adults who first manifest GD during or after adolescence.

110. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I have observed an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years, and young "detransitioners" (individuals in the process of reidentifying with their birth sex after having undergone a gender transition) are now receiving increasing attention in both clinical literature and social media channels.

111. Almost all scientific articles on this topic have appeared within the last few years. Perhaps this historic lack of coverage is not entirely surprising – one academic who undertook an extensive review of the available scientific literature in 2021 noted that the phenomenon was "socially controversial" in that it "poses significant professional and bioethical challenges for those clinicians working in the field of gender dysphoria." (Expósito Campos 2021 at 270.) This review reported on the multiple reasons for why individuals were motivated to detransition, which included coming to "understand[ ] how past trauma, internalized sexism, and other psychological difficulties influenced the experience of GD."

112. In 2021, Lisa Littman of Brown University conducted a ground-breaking study of

100 teenage and young adults who had transitioned and lived in a transgender identity for a number of years, and then "detransitioned" or changed back to a gender identity matching their sex. Littman noted that the "visibility of individuals who have detransitioned is new and may be rapidly growing." (Littman 2021 at 1.) Of the 100 detransitioners included in Littman's study, 60% reported that their decision to detransition was motivated (at least in part) by the fact that they had become more comfortable identifying as their natal sex, and 38% had concluded that their gender dysphoria was caused by something specific such as trauma, abuse, or a mental health condition. (Littman 2021 at 9.)

113. A significant majority (76%) did not inform their clinicians of their detransition. (Littman 2021 at 11.)

114. A similar study that recruited a sample of 237 detransitioners (the large majority of whom had initially transitioned in their teens or early twenties) similarly reported that a common reason for detransitioning was the subject's conclusion that his or her gender dysphoria was related to other issues (70% of the sample). (Vandenbussche 2021.)

115. The existence of increasing numbers of youth or young adult detransitioners has also been recently noted by Dr. Edwards-Leeper and Dr. Anderson. (Edwards-Leeper & Anderson 2021.) Edwards-Leeper and Anderson noted "the rising number of detransitioners that clinicians report seeing (they are forming support groups online)" which are "typically youth who experienced gender dysphoria and other complex mental health issues, rushed to medicalize their bodies and regretted it." Other clinicians working with detransitioners have also noted the recent phenomenon. (Marchiano 2020.)

116. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle

2020; Littman 2021; Vandenbussche 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo 2018). As gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

117. A recent study from a UK adult gender clinic observed that 6.9% of those treated with gender-affirmative interventions detransitioned within 16 months, and another 3.4% had a pattern of care suggestive of detransition, yielding a rate of probable detransition in excess of 10%. Another 21.7%, however, disengaged from the clinic without completing their treatment plan. While some of these individuals later re-engaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." (Hall et al. 2021.)

118. Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for an average 5 years (17 months-10 years) prior to discontinuing. Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: "Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields" (Boyd et al. 2022 at 15.) Indeed, given that regret may take up to 8-11 years to materialize (Dhejne et al., 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but the Littman and Vandenbussche studies in 2021 both report that detransitioners from the recently transitioning cohorts feel they were rushed into medical gender-affirmative interventions with irreversible effects, often without the benefit of appropriate, or in some instances any, psychologic exploration.

VII. TRANSITION AND AFFIRMATION ARE IMPORTANT PSYCHOLOGICAL AND MEDICAL INTERVENTIONS THAT CHANGE GENDER IDENTITY OUTCOMES.

A. If both a typical gender or a transgender long-term gender identity outcome are possible for a particular patient, the alternatives are not medically neutral.

119. Where a juvenile experiences gender dysphoria, the gender identity that is stabilized will have a significant impact on the course of their life. Living in a transgender identity for a time will make desistance, if it is ever considered, more difficult to accomplish.

120. If the juvenile desists from the gender dysphoria and becomes reasonably comfortable with a gender identity congruent with their sex—the most likely outcome from a statistical perspective absent affirming intervention—the child will not require ongoing pharmaceutical maintenance and will not have their fertility destroyed post-puberty.

121. However, if the juvenile persists in a transgender identity, under current practices, the child is most likely to require regular administration of hormones for the rest of their lives, exposing them to significant physical, mental health, and relational risks (which I detail in Section IX below), as well as being irreversibly sterilized chemically and/or surgically. The child is therefore rendered a "patient for life" with complex medical implications to further a scientifically unproven course of treatment.

B. Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance.

122. Social transition has a critical effect on the persistence of gender dysphoria. It is evident from the scientific literature that engaging in therapy that encourages social transition before or during puberty—which would include participation on athletic teams designated for the opposite sex—is a psychotherapeutic intervention that dramatically changes outcomes. A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." (Guss et al. 2015 at 421.) Similarly, a comparison

of recent and older studies suggests that when an "affirming" methodology is used with children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker 2018 at 7.) Olson's publication not only affirmed Zucker's observation but provided very low rates of retransition or desistence among those socialized before or after grade school years. (Olson et al, 2022.)

123. Indeed, a review of multiple studies of children treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, at least in the case of boys. That is, while, as I review above, studies conducted before the widespread use of social transition for young children reported desistance rates in the range of 80-98%, a more recent study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker 2018 at 7[7]; Steensma et al. 2013.[8]) Another researcher observed that a partial or complete gender social transition prior to puberty "proved to be a unique predictor of persistence." (Singh et al. 2021 at 14.)

124. Some vocal practitioners of prompt affirmation and social transition even proudly claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross-gender identification desist in that identification and return to a gender identity consistent with their biological sex.[9] This is a very large change as compared to the desistance rates documented apart

[7] Zucker found social transition by the child to be strongly correlated with persistence for natal boys, but not for girls. (Zucker 2018 at 5.)

[8] Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma 2013 at 584.

[9] *See, e.g.*, Ehrensaft 2015 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have

from social transition.

125. Even voices generally supportive of prompt affirmation and social transition are acknowledging a causal connection between social transition and this change in outcomes. As the Endocrine Society recognized in its 2017 Guidelines: "If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty. . . [S]ocial transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence." (Hembree et al. 2017 at 3879.) The fact is that these unproven interventions with the lives of kids and their families have systematically documented outcomes. Given this observed phenomenon, I agree with Dr. Ken Zucker who has written that social transition in children must be considered "a form of psychosocial treatment." (Zucker 2020 at 1.)

126. Moreover, as I review below, social transition cannot be considered or decided alone. Studies show that engaging in social transition starts a juvenile on a "conveyor belt" path that almost inevitably leads to the administration of puberty blockers, which in turn almost inevitably leads to the administration of cross-sex hormones. The emergence of this well- documented path means that the implications of taking puberty blockers *and* cross-sex hormones must be taken into account even where "only" social transition is being considered or requested by the child or family. As a result, there are a number of important "known risks" associated with social transition.

C. Administration of puberty blockers is a powerful medical and psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance on the historically observed timeline.

127. It should be understood that puberty blockers are usually administered to early-stage adolescents as part of a path that includes social transition. Yet medicine does not know what the long-term health effects on bone, brain, and other organs are of a "pause" between ages 11-16.

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no documentation of a child who has 'desisted' and asked to return to his or her assigned gender."

Medicine also does not know if the long-term effects of these compounds are different in boys than in girls. The mental health professional establishment likewise does not know the long-term effects on coping skills, interpersonal comfort, and intimate relationships of this "pause" while one's peers are undergoing their maturational gains in these vital arenas of future mental health. I address medical, social, and mental health risks associated with the use of puberty blockers in Section X. Here, I note that the data strongly suggests that the administration of puberty blockers, too, must be considered to be a component of a "psychosocial treatment" with complex implications, rather than simply a "pause."

128. Multiple studies show that the large majority of children who begin puberty blockers go on to receive cross-sex hormones. (de Vries 2020 at 2.) A recent study by the Tavistock and Portman NHS Gender Identity Development Service (UK)—the world's largest gender clinic—found that 98% of adolescents who underwent puberty suppression continued on to cross-sex hormones. (Carmichael et al 2021 at 12.)[10]

129. These studies demonstrate that going on puberty blockers virtually eliminates the possibility of desistance in juveniles. Rather than a "pause," puberty blockers appear to act as a psychosocial "switch," decisively shifting many children to a persistent transgender identity. Therefore, as a practical and ethical matter, the decision to put a child on puberty blockers must be considered as the equivalent of a decision to put that child on cross-sex hormones, with all the considerations and informed consent obligations implicit in that decision.

[10] *See also* Brik 2020 where Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones.

VIII. TRANSITION AND AFFIRMATION ARE EXPERIMENTAL THERAPIES THAT HAVE NOT BEEN SHOWN TO IMPROVE MENTAL OR PHYSICAL HEALTH OUTCOMES BY YOUNG ADULTHOOD.

130. It is undisputed that children and adolescents who present with gender dysphoria exhibit a very high level of mental health comorbidities. (Section III.C.) Whether the gender dysphoria is cause or effect of other diagnosed or undiagnosed mental health conditions, or whether these are merely coincident comorbidities, is hotly disputed, but the basic fact is not.

A. The knowledge base concerning therapies for gender dysphoria is "very low quality."

131. It is important for all sides to admit that the knowledge base concerning the causes and treatment of gender dysphoria has low scientific quality. In evaluating claims of scientific or medical knowledge, it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data comprising:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future. Reliance on well-known or well-credentialled "experts," or the head of a gender clinic, is sometimes referred to as eminence-based medicine. Their opinions do not garner as much respect from professionals as what follows;

b. A single case or series of cases (what could be called anecdotal evidence) (Levine 2016 at 239.);

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

132. Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment. [T]he proposed benefits of treatment to eliminate gender discordance … must be carefully weighed against … possible deleterious effects." (Adelson et al. at 968–69.) Similarly, the American Psychological Association has stated, "because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children." (APA 2015 at 842.)

133. Critically, "there are no randomized control trials with regard to treatment of children with gender dysphoria." (Zucker 2018 at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases, or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine 2016 at 239.)

134. Within the last two years, at least five formal, independent, systematic evidence reviews concerning hormonal interventions for gender dysphoria have been conducted. All five found all of the available clinical evidence to be very low quality.

135. The British National Health Service (NHS) commissioned formal "evidence reviews" of all clinical papers concerning the efficacy and safety of puberty blockers and cross- sex

hormones as treatments for gender dysphoria. These evidence reviews were performed by the U.K. National Institute for Health and Care Excellence (NICE), applying the respected "GRADE" criteria for evaluating the strength of clinical evidence.

136. Both the review of evidence concerning puberty blockers and the review of evidence concerning cross-sex hormones were published in 2020, and both found that *all* available evidence as to both efficacy and safety was "very low quality" according to the GRADE criteria. (NICE 2021a; NICE 2021b.) This work is sometimes referred to as the Cass Report.[11] "Very low quality" according to GRADE means there is a high likelihood that the patient *will not experience* the hypothesized benefits of the treatment. (Balshem et al. 2011.)

137. Similarly, the highly respected Cochrane Library—the leading source of independent systematic evidence reviews in health care—commissioned an evidence review concerning the efficacy and safety of hormonal treatments now commonly administered to "transitioning transgender women" (i.e., testosterone suppression and estrogen administration to biological males). That review, also published in 2020, concluded that "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." (Haupt et al. 2020 at 2.) It must be understood that both the NICE and the Cochrane reviews considered *all* published scientific studies concerning these treatments. Similarly, McMasters University's skillful methodological unit recently reached the same conclusion (Brignardello-Peterson, & Wiercioch, 2022).

138. As to social transition, as I have noted above, considerable evidence suggests that socially transitioning a pre-pubertal child puts him or her on a path from which very few children escape—a path which includes puberty blockers and cross-sex hormones before age 18. And for

[11] https://cass.independent-review.uk/publications/interim-report/

some, surgery before the age of majority. A decision about social transition for a child must be made in light of what is known and what is unknown about the effects of those expected future interventions. Social transition, therefore, is not merely reversible behavioral change. It is the beginning of a medically dependent future and should be explained as such.

139. I discuss safety considerations in Section IX below. Here, I detail what is known about the effectiveness of social and hormonal transition and affirmation to improve the mental health of individuals diagnosed with gender dysphoria.

B. Youth who adopt a transgender identity show no durable improvement in mental health after social, hormonal, or surgical transition and affirmation.

140. As I noted above, the evidence reviews for the efficacy and safety of hormonal interventions published in 2020 concluded that the supporting evidence is so poor that there is "a high likelihood that the patient will not experience the hypothesized benefits of the treatment." There is now some concrete evidence that, on average, they do not experience those benefits.

141. An important paper published in 2021 by Tavistock clinic clinicians provided the results of the first longitudinal study that measured widely used metrics of general psychological function and suicidality before commencement of puberty blockers, and then at least annually after commencing puberty blockers. After up to three years, they "found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self- report (YSR) of overall problems, internalizing or externalizing problems or self-harm" as compared to the pre-puberty-blocker baseline evaluations. "Outcomes that were not formally tested also showed little change." (Carmichael at al. 2021, at 18-19.) Similarly, a study by Bränström and Pachankis of the case histories of a set of individuals diagnosed with GD in Sweden found no positive effect on mental health from hormonal treatment. (Landen 2020.)

142. A cohort study by authors from Harvard and Boston Children's Hospital found that youth and young adults (ages 12-29) who self-identified as transgender had an elevated risk of

depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services. (Reisner et al. 2015 at 6.) Similarly, a recent longitudinal study of transgender and gender diverse youth and young adults in Chicago found rates of alcohol and substance abuse "substantially higher than those reported by large population-based studies of youth and adults." (Newcomb et al. 2020 at 14.) Members of the clinical and research team at the prominent Dutch VU University gender dysphoria center recently compared mental health metrics of two groups of subjects before (mean age 14.5) and after (mean age 16.8) puberty blockers. But they acknowledged that the structure of their study meant that it "can . . . not provide evidence about . . . long-term mental health outcomes," and that based on what continues to be extremely limited scientific data, "Conclusions about the long-term benefits of puberty suppression should . . . be made with extreme caution." In other words, we just don't know. (van der Miesen et al. 2020, at 703.)

143. Kiera Bell, who was diagnosed with gender dysphoria at the Tavistock Clinic, given cross-sex hormones, and treated by mastectomy, before desisting and reclaiming her female gender identity, and a Swedish teen girl who appeared in a recent documentary after walking that same path, have both stated that they feel that they were treated "like guinea pigs," experimental subjects. They are not wrong.

144. A recent two-year prospective uncontrolled multisite NIMH study of 315 adolescents found that at the average age of 18 the primary benefit of hormones was happiness with their aesthetic appearance. The effects on depression and anxiety were very small and highly variable. There were two suicides in the study population. (Chen et al 2023.) This work did not address the relevant long term mental health outcomes of such treatment before their two-year finding.

However, in May 2022 a group from Sweden performed a systematic review of the mental health effects of hormonal transition because they asserted that the literature did not provide sufficient evidence to inform clinical decision making. They concluded that candidates for hormones had a high percentage of mental health problems, and the methodological quality of the 32 papers studied (representing between 3,000 and 4,000 patients) did not allow for a firm answer as to whether mental health was improved by hormonal treatment. (Thompson et al 2022).

C. Long-term mental health outcomes for individuals who persist in a transgender identity are poor.

145. The responsible MHP cannot focus narrowly on the short-term happiness of the young patient but must instead consider the happiness and health of the patient from a "life course" perspective. When we look at the available studies of individuals who continue to inhabit a transgender identity across adult years, the results are strongly negative.

146. In the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated rates of substance abuse as well as suicide. (Levine 2017, at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. (Dhejne et al. 2011; Simonsen et al. 2016.) The Swedish follow-up study similarly found a suicide rate in the post-SRS population 19.1 times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine 2017, at 10.)

147. A study in the American Journal of Psychiatry reported high mental health utilization patterns of adults for ten years after surgery for approximately 35% of patients. (Bränström & Pachankis, 2020.) Indeed, earlier Swedish researchers in a long-term study of all patients provided with SRS over a 30-year period (median time since SRS of > 10 years) concluded that individuals who have SRS exhibit such poor mental health that they should be provided very long-term

psychiatric care as the "final" transition step of SRS. (Dhejne et al. 2011, at 6-7.) Unfortunately, across the succeeding decade, in Sweden and elsewhere their suggestion has been ignored.

148. The most recent all-cause mortality study from the UK found a significant excess of deaths among trans individuals compared to age matched controls of both sexes. External causes of death (suicide, homicide, accidental poisoning) were particularly higher than control groups (Jackson et al 2023). The risk of death was 34% greater among trans identified individuals than the general population. The mean age of the trans group was 36 years.

149. I will note that these studies do not tell us whether the subjects first experienced gender dysphoria as children, adolescents, or adults, so we cannot be certain how their findings apply to each of these subpopulations which represent quite different pathways. But in the absence of knowledge, we should be cautious.

150. Meanwhile, no studies show that affirmation of pre-pubescent children or adolescents leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does "watchful waiting" or ordinary therapy.

151. The many studies that I have cited here warn us that as we look ahead to the patient's life as a young adult and adult, the prognosis for the physical health, mental health, and social well-being of the child or adolescent who transitions to live in a transgender identity is not good. Gender dysphoria is not "easily managed" when one understands the marginalized, vulnerable physical, social, and psychological status of adult trans populations and their premature death patterns.

IX. TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MAY INCREASE, THE RISK OF SUICIDE.

A. The risk of suicide among transgender youth is confused and exaggerated in the public mind.

152. While suicide is closely linked to mental health, I comment on it separately because rhetoric relating to suicide figures so prominently in debates about responses to gender dysphoria.

153. At the outset, I will note that any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is extremely rare, and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. Any suggestion otherwise is misinformed. Our focus for this topic, then, is on adolescents and adults.

154. Some authors have reported rates of suicidal thoughts and behaviors among trans-identifying teens or adults ranging from 25% to as high as 52%, generally through non-longitudinal self-reports obtained from non-representative survey samples. (Toomey et al. 2018.) Some advocates of affirmative care assert that the only treatment to avoid this serious harm is to affirm gender identity. Contrary to these assertions, no studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a "watchful waiting" or a psychotherapeutic model of response, as I have described above. Rhetorical references to figures such as 40%—and some published studies—confuse suicidal thoughts and actions that represent a cry for help, manipulation, or expression of rage with serious attempts to end life. Such statements or studies ignore a crucial and long-recognized distinction.

155. I have included suicidality in my discussion of mental health above. Here, I focus on actual suicide. Too often, in public comment suicidal thoughts are blurred with suicide. Yet the available data tells us that suicide among children and youth suffering from gender dysphoria is extremely rare.

156. An important analysis of data covering patients as well as those on the waiting list (and thus untreated) at the UK Tavistock gender clinic—the world's largest gender clinic—found a total of only four completed suicides across 11 years' worth of patient data, reflecting an estimated cumulative 30,000 patient-years spent by patients under the clinic's care or on its waiting list. This corresponded to an annual suicide rate of 0.013%. The proportion of individual patients who died

by suicide was 0.03%, which is orders of magnitude smaller than trans adolescents who self-report suicidal behavior or thoughts on surveys. (Biggs 2022b.)

157. Thus, only a minute fraction of trans-identifying adolescents who report thoughts or conduct considered to represent "suicidality" commit suicide. I agree with Dr. Zucker that the assertion by, for example, Karasic and Ehrensaft (2015) that completed suicides among transgender youth are "alarmingly high" "has no formal and systematic empirical basis." (Zucker 2019 at 3.)

158. Professor Biggs of Oxford, author of the study of incidence of suicide among Tavistock clinic patients, rightly cautions that it is "irresponsible to exaggerate the prevalence of suicide." (Biggs 2022b at 4.) It is my opinion that telling parents—or even allowing them to believe from their internet reading—that they face a choice between "a live son or a dead daughter" is both factually wrong and unethical. Informed consent requires clinicians to tell the truth and ensure that their patients understand the truth. To be kind, the clinicians who believe such figures represent high risk of ultimate suicide in adolescence simply do not know the truth; they are ill-informed.

B. Transition of any sort has not been shown to reduce levels of suicide.

159. Every suicide is a tragedy, and steps that reduce suicide should be adopted. I have noted above that suicidality (that is, suicidal thoughts or behaviors, rather than suicide) is common among transgender adolescents and young adults before, during, and after social and medical transition. If a medical or mental health professional believes that an individual he or she is diagnosing or treating for gender dysphoria presents a suicide risk, in my view it is unethical for that professional merely to proceed with treatment for gender dysphoria and hope that "solves the problem." Rather, that professional has an obligation to provide or refer the patient for evidence-based therapies for addressing depression and suicidal thoughts that are well-known to the profession. (Levine 2016, at 242.)

160. This is all the more true because there is in fact no evidence that social and/or medical

transition reduces the risk or incidence of actual suicide. As there are no long-term comparative studies of gender dysphoric adolescents with suicidal ideation, per se, let alone a comparative study of those who were given hormones and those who did not take hormones, there is no scientific basis for declaring affirmative care as reducing suicidal risk. In his analysis of those who were patients of or on the waiting list of the Tavistock clinic, Professor Biggs found that the suicide rate was not higher among those on the clinic's waiting list (and thus as-yet untreated), than for those who were patients under care. (Biggs 2022b.) And as corrected, Bränström and Pachankis similarly acknowledge that their review of records of GD patients "demonstrated no advantage of surgery in relation to . . . hospitalizations following suicide attempts." (I assume for this purpose that attempts that result in hospitalization are judged to be so serious as to predict a high rate of future suicide if not successfully addressed.")[12] Long-term life in a transgender identity, however, correlates with very high rates of completed suicide.

161. As with mental health generally, the patient, parent, or clinician fearing the risk of suicide must consider not just the next month or year, but a life course perspective.

162. There are now four long-term studies that analyze completed suicide among those living in transgender identities into adulthood. The results vary significantly but are uniformly highly negative. Dhejne reported a long-term follow-up study of subjects after sex reassignment surgery. Across the thirty-year study, subjects who had undergone SRS committed suicide at 19.1 times the expected rate compared to general population controls matched by age and both sexes. MtF subjects committed suicide at 13.9 times the expected rate, and FtM subjects committed suicide at 40.0 times the expected rate. (Dhejne et al. 2011 Supplemental Table S1.)

[12] Turban et al. (2020) has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

163. Asscheman, also writing in 2011, reported results of a long-term follow-up of all transsexual subjects of the Netherlands' leading gender medicine clinic who started cross-sex hormones before July 1, 1997, a total of 1331 patients. Due to the Dutch system of medical and death records, extensive follow-up was achieved. Median follow-up period was 18.5 years. The mortality rate among MtF patients was 51% higher than among the age-matched general population; the rate of completed suicide among MtF patients was six times that of the age- matched general population. (Asscheman et al. 2011.)

164. Importantly, Asscheman et al. found that "No suicides occurred within the first 2 years of hormone treatment, while there were six suicides after 2-5 years, seven after 5-10 years, and four after more than 10 years of CSH treatment at a mean age of 41.5 years." (Asscheman et al. 2011 at 637-638.) This suggests that studies that follow patients for only a year or two after treatment are insufficient. Asscheman et al.'s data suggest that such short-term follow-up is engaging only with an initial period of optimism, and it will simply miss the feelings of disillusion and the increase in completed suicide that follows in later years.

165. A retrospective, long-term study published in 2020 of a very large cohort (8263) of patients referred to the Amsterdam University gender clinic between 1972 and 2017 found that the annual rate of completed suicides among the transgender subjects was "three to four times higher than the general Dutch population." "[T]he incidence of observed suicide deaths was almost equally distributed over the different stages of treatment." The authors concluded that "vulnerability for suicide occurs similarly in the different stages of transition." (Wiepjes et al. 2020.) In other words, neither social nor medical transition reduced the rate of suicide.

166. As with Asscheman et al., Wiepjes et al. found that the median time between start of hormones and suicide (when suicide occurred) was 6.1 years for natal males, and 6.9 years for natal females. Again, short- or even medium-term studies will miss this suicide phenomenon.

167. A 2021 study analyzed the case histories of a cohort of 175 gender dysphoria patients treated at one of the seven UK adult gender clinics who were "discharged" (discontinued as patients) within a selected one-year period. The authors reported the rather shocking result that 7.7% (3/39) of natal males who were diagnosed and admitted for treatment, and who were between 17 and 24 years old, were "discharged" because they committed suicide *during* treatment. (Hall et al. 2021, Table 2.)

168. None of these studies demonstrates that the hormonal or surgical intervention *caused* suicide. That is possible, but as we have seen, the population that identifies as transgender suffers from a high incidence of comorbidities that correlate with suicide. What these studies demonstrate—at the least—is that this remains a troubled population in need of extensive and careful psychological care that they generally do not receive, and that neither hormonal nor surgical transition and "affirmation" resolve their underlying problems and put them on the path to a stable and healthy life.

169. In sum, claims that affirmation will reduce the risk of suicide for children and adolescents are not based on science. Instead, transition of any sort must be justified, if at all, as a life-enhancing measure, not a lifesaving measure. (Levine 2016, at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

X. HORMONAL INTERVENTIONS ARE EXPERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.

170. A number of voices in the field assert that puberty blockers act merely as a "pause" in the process of puberty-driven maturation, suggesting that this hormonal intervention has been proven to be fully reversible. This is also an unproven belief.

171. On the contrary, no studies have been done that meaningfully demonstrate that either puberty blockers or cross-sex hormones, as prescribed for gender dysphoria, are safe in other than the short run. No studies have attempted to determine whether the effects of puberty blockers, as

currently being prescribed for gender dysphoria, are fully reversible. There are only pronouncements. In fact, there are substantial reasons for concern that these hormonal interventions are not safe. Multiple researchers have expressed concern that the full range of possible harms have not even been correctly conceptualized.

172. Because, as I have explained in Section VI, recent evidence demonstrates that pre-pubertal social transition almost always leads to progression on to puberty blockers which in turn almost always leads to the use of cross-sex hormones, physicians bear the ethical responsibility for a thorough informed consent process for parents and patients that includes this fact and its full implications. Informed consent does not mean sharing with the parents and patients what the doctor believes: it means sharing what is known and what is not known about the intervention. So much of what doctors believe is based on mere trust in what they have been taught. Neither they themselves nor their teachers may be aware of the scientific foundation and scientific limitations of what they are recommending.

A. Use of puberty blockers has not been shown to be safe or reversible for gender dysphoria.

173. As I noted above, the recent very thorough literature review performed for the British NHS concluded that *all* available clinical evidence relating to "safety outcomes" from administration of puberty blockers for gender dysphoria is of "very low certainty." (NHS 2020, at 6.)

174. In its 2017 Guidelines, the Endocrine Society cautioned that "in the future we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols" including "careful assessment of . . . the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development)." (Hembree et al. 2017, at 3874.) No such "careful" or "rigorous" evaluation

of these very serious safety questions has yet been done.

175. Some advocates assume that puberty blockers are "safe" because they have been approved by the Food and Drug Administration (FDA) for use to treat precocious puberty—a rare condition in which the puberty process may start at eight or younger. No such conclusion can be drawn. As the "label" for Lupron (one of the most widely prescribed puberty blockers) explains, the FDA approved the drug only *until* the "age was appropriate for entry into puberty." The study provides no information at all as to the safety or reversibility of instead *blocking* healthy, normally-timed puberty's beginning, and *throughout* the years that body-wide continuing changes normally occur. Given the physical, social, and psychological dangers to the child with precocious puberty, drugs like Lupron are effective in returning the child to a puerile state like their peers without a high incidence of significant side effects—that is, they are "safe" to reverse the condition. But use of drugs to suppress normal puberty has multiple organ system effects whose long-term consequences have not been investigated.

176. Systematic data reviews are scientifically more reliable than individual reports with definable methodologic limitations. Without quoting extensively from the reviews done by Sweden, Finland, UK, and McMasters University, suffice it to say that their conclusions agree that the risks of puberty suppression and cross-sex hormones outweigh the possible benefits. They also point to the great unexplained increase in incidence of gender dysphoria, the increased incidence of detransition and regret, and the lack of evidence of efficacy.[13] (Swedish National Board of Health and Welfare, 2022).

13 https:/www.sociialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-7799.pdf

177. **Fertility**: The Endocrine Society Guidelines rightly say that research is needed into the effect of puberty blockade on "gonadal function" and "sexual development." The core purpose and function of puberty blockers is to prevent the maturation of the ovaries or testes, the sources of female hormones and male hormones when stimulated by the pituitary gland. From this predictable process fertility is accomplished within a few years. Despite widespread assertions that puberty blockers are "fully reversible," there has been no study published on the critical question of whether patients ever develop normal levels of fertility if puberty blockers are terminated after a "prolonged delay of puberty." The 2017 Endocrine Society Guidelines are correct that are no data on achievement of fertility "following prolonged gonadotropin suppression" (that is, puberty blockade). (Hembree et al. 2017, at 3880.)

178. **Bone strength**: Multiple studies have documented adverse effects from puberty blockers on bone density. (Klink et al. 2015; Vlot et al. 2016; Joseph et al. 2019.) The most recent found that after two years on puberty blockers, the bone density measurements for a significant minority of the children had declined to clinically concerning levels. Density in the spines of some subjects fell to a level found in only 0.13% of the population. (Biggs 2021.) Some other studies have found less-concerning effects on bone density. While the available evidence remains limited and conflicting, it is not possible to conclude that the treatment is "safe."

179. **Brain development:** Important neurological growth and development in the brain occurs across puberty. The anatomic and functional effect on brain development of blocking the natural puberty process has not been well studied. A prominent Australian clinical team recently expressed concern that "no data were (or are) available on whether delaying the exposure of the brain to a sex steroid affects psychosexual, cognitive, emotional, or other neuropsychological maturation." (Kozlowska et al. 2021, at 89.) In my opinion, given the observed correlation between puberty and brain development, the default hypothesis must be that there *would* be a negative

impact. For the purpose of protecting patients all over the world, the burden of proof should be on advocates to first demonstrate to a reasonable degree of certainty that brain structure and its measurable cognitive and affect processing are not negatively affected. This recalls the ethical principle: Above All Do No Harm.

180. The Endocrine Society Guidelines acknowledge as much, stating that side effects of pubertal suppression "may include . . . unknown effects on brain development," that "we need more rigorous evaluations of . . . the effects of prolonged delay of puberty in adolescents on . . . the brain (including effects on cognitive, emotional, social, and sexual development)," and stating that "animal data suggests there may be an effect of GnRH analogs [puberty blockers] on cognitive function." (Hembree et al. 2017, at 3874, 3882, 3883.) Given this concern, one can only wonder why this relevant question has not been scientifically investigated in a large group of natal males and females.

181. There has been a longitudinal study of one natal male child, assessed before, and again 20 months after, puberty suppression was commenced. It reported a reduction in the patient's "global IQ," measured an anomalous absence of certain structural brain development expected during normal male puberty, and hypothesized that "a plausible explanation for the G[lobal] IQ decrease should consider a disruption of the synchronic [i.e., appropriately timed] development of brain areas by pubertal suppression." (Schneider et al. 2017, at 7.) This should cause parents and practitioners serious concern.

182. Whether any impairment of brain development is "reversed" upon later termination of puberty blockade has, to my knowledge, not been studied at all. As a result, assertions by medical or mental health professionals that puberty blockade is "fully reversible" are unjustified and based on hope rather than science.

183. Without a number of additional case studies—or preferably statistically significant clinical studies—two questions remain unanswered: Are there brain anatomic or functional impairment from puberty blockers? And are the documented changes reversed over time when puberty blockers are stopped? With these questions unanswered, it is impossible to assert with certainty that the effects of this class of medications are "fully reversible." Such an assertion is another example of ideas based on beliefs rather than on documentation, on hope not science.

184. **Psycho-social harm**: Puberty is a time of stress, anxiety, bodily discomfort during physical development, and identity formation for *all* humans. No careful study has been done of the long-term impact on the young person's coping skills, interpersonal comfort, and intimate relationships from remaining puerile for, e.g., two to five years while one's peers are undergoing pubertal transformations, and of then undergoing an artificial puberty at an older age. However, pediatricians and mental health professionals hear of distress, concern, and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines witnessing their peers developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine 2018 at 9.) Social anxiety and social avoidance are common findings in the evaluation of trans-identified children and teens. Are we expected to believe that creating years of being further different than their peers has no lasting internal consequences? Do we ignore Adolescent Psychiatry's knowledge of the importance of peer groups among adolescents?

185. We simply do not know what all the psychological impacts of NOT grappling with puberty at the ordinary time may be, because it has not been studied. And we have no information as to whether that impact is "fully reversible." We should at least consider that the normal pubertal ushering of an adolescent into the world of sexual attraction, romantic preoccupations, sexual

desires, and forays into interpersonal intimate relationships can be a positive experience for an untreated trans identified child. In contrast, puberty is presented solely as a negative process to be avoided by puberty blockers. In psychiatry we have the concept that conflict is inevitable, and its resolution strengthens a person's capacities to deal with the future. This applies to individuals of any age.

186. In addition, since the overwhelming proportion of children who begin puberty blockers continue on to cross-sex hormones, it appears that there is an important element of "psychological irreversibility" in play. The question of to what extent the physical and developmental impacts of puberty blockers might be reversible is an academic one, if psycho-social realities mean that very few patients well ever be able to make that choice once they have started down the road of social transition and puberty blockers.

B. Use of cross-sex hormones in adolescents for gender dysphoria has not been shown to be medically safe except in the short term.

187. As with puberty blockers, all evidence concerning the safety of extended use of cross-sex hormones is of "very low quality." The U.K. NICE evidence review cautioned that "the safety profiles" of cross-sex hormone treatments are "largely unknown," and that several of the limited studies that do exist reported high numbers of subjects "lost to follow-up," without explanation—a worrying indicator. (NICE 2020b.)

188. The 2020 Cochrane Review reported that: "We found insufficient evidence to determine the . . . safety of hormonal treatment approaches for transgender women in transition." (Haupt et al. 2020 at 4.) Even the Endocrine Society tagged all its recommendations for the administration of cross-sex hormones as based on "low quality evidence." (Hembree et al. 2017 at 3889.)

189. **Sterilization**: It is undisputed, however, that harm to the gonads is an expected effect, to the extent that it must be assumed that cross-sex hormones will sterilize the patient. Thus, the Endocrine Society 2017 Guidelines caution that "[p]rolonged exposure of the testes to estrogen has been associated with testicular damage," that "[r]estoration of spermatogenesis after prolonged estrogen treatment has not been studied," and that "[i]n biological females, the effect of prolonged treatment with exogenous testosterone upon ovarian function is uncertain." (Hembree et al. 2017, at 3880.)[14]

190. The Guidelines go on to recommend that the practitioner counsel the patient about the (problematic and uncertain) options available to collect and preserve fertile sperm or ova before beginning cross-sex hormones. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender transition for any patient. What has been documented is the low rate of acceptance of banking sperm or ova in this population, which is an expensive ongoing process.

191. **Sexual response**: Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who did not go through puberty consistent with their sex and are then put on cross-sex hormones face significantly diminished sexual response as they enter adulthood and are unable ever to experience orgasm. In the case of males, the cross-sex administration of estrogen limits penile genital growth and function. In the case of females, prolonged exposure to exogenous testosterone impairs vaginal function. Much has been written

[14] *See also* Guss et al. 2015 at 4 ("a side effect [of cross-sex hormones] may be infertility") and at 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman et al. 2015 at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine 2018, at 6.) At the same time, prolonged exposure of females to exogenous testosterone often increases sexual drive to a distracting degree. It is likely that parents and physicians are uncomfortable discussing any aspects of genital sexual activity with patients. And these young often interpersonally sexually inexperienced patients are both too embarrassed to talk about the subject and too young to seriously consider the topic.

192. **Cardiovascular harm**: Several researchers have reported that cross-sex hormones increase the occurrence of various types of cardiovascular disease, including strokes, blood clots, and other acute cardiovascular events. (Getahun et al. 2018; Guss et al. 2015; Asscheman et al. 2011.) With that said, I agree with the conclusion of the Endocrine Society committee (like that of the NICE Evidence Review) that: "A systematic review of the literature found that data were insufficient (due to very low-quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or venous thromboembolism in transgender males. Future research is needed to ascertain the potential harm of hormonal therapies." (Hembree et al. 2017 at 3891.) Future research questions concerning long-term harms need to be far more precisely defined. The question of whether cross-sex hormones are safe for adolescents and young adults cannot be answered by analogies to hormone replacement therapy in menopausal women (which is not a cross-sex usage). Medicine has answered safety questions for menopausal women in terms of cancer and cardiovascular safety: at what dose, for what duration, and at what age range. The science of endocrine treatment of gender dysphoric youth is being bypassed by short-term clinical impressions of safety even though physicians know that cardiovascular and cancer processes often develop over many years.

193. Further, in contrast to administration for menopausal women, hormones begun in

adolescence are likely to be administered for four to six decades. The published evidence of adverse impact, coupled with the lack of data sufficient to reach a firm conclusion, make it irresponsible to assert that cross-sex hormones "are safe." We must not forget the diverse sources of evidence of premature death among the trans communities.

194. **Harm to family and friendship relationships:** As a psychiatrist, I recognize that mental health is a critical part of health generally, and that relationships cannot be separated from and profoundly impact mental health. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine 2017, at 5.) My concerns about this are based on decades of observations in my professional work with patients and their families. It is important to recognize that the tradition throughout medicine is the focus on the patient. This is true in adolescent medicine as well and seems natural and self-evident. However, when a trans identity occurs in a family, every member—parents, siblings, grandparents, etc—is affected. I am used to watching parents become depressed, siblings take sides, and family dysfunction increase. It is rare to find a medical or mental health professional whose work reflects that each of these family members are deeply connected and share in the uncertainties that are embedded in any trans identity. There may be too much focus on the trans person as a patient and not enough as a trans person developing in an interpersonal, ever-changing matrix called a family.

195. **Sexual-romantic harms associated with transition:** After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate

relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential mates lose interest. When a trans person does not pass well, options are likely further diminished. But regardless of a person's appearance, these adults soon learn that many of their dates are looking for exotic sexual experiences rather than genuinely loving relationships. (Levine 2017, at 5, 13; Levine 2013, at 40.)

C. The timing of harms.

196. The multi-year delay between start of hormones and the spike in completed suicide observed by Professor Biggs in the Tavistock data (as discussed in Section VIII above) warns us that the safety and beneficence of these treatments cannot be judged based on short-term studies, or studies that do not continue into adulthood. Similarly, several of the harms that I discuss above would not be expected to manifest until the patients reaches at least middle-age. For example, stroke or other serious cardiovascular event is a complication that is unlikely to manifest during teen years even if its likelihood over the patient's lifetime has been materially increased via obesity, lipid abnormalities, and smoking. Regret over sterilization or over an inability to form a stable romantic relationship may occur sooner. Psychological challenges of being a trans adult may become manifest after the medical profession is only doing routine follow up care—or, in many cases, has lost contact with the patient altogether. Because few, if any, clinics in this country are conducting systematic long-term follow-up with their child and adolescent patients, the doctors who counsel, prescribe, or perform hormonal and surgical therapies are unlikely ever to become aware of the later negative life impacts, however severe. These concerns are compounded by the findings in the recent "detransitioner" research that 76% did not inform their clinicians of their detransition. (Littman 2021.)

197. The possibility that steps along the transition and affirmation pathway, while lessening the pain of gender dysphoria in the short term, could lead to additional sources of crippling

emotional and psychological pain, are too often not considered by advocates of social transition and not considered at all by the trans child. (Levine 2016, at 243.) Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view. Hopefully, so will the child's physician.

198. Individual patients often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health co-morbidities. In this way, transition can prevent them from mastering personal challenges at the appropriate time or directly addressing conditions that require treatment. When the hoped-for "vanishing" of other mental health or social difficulties does not occur, disappointment, distress, and depression may ensue. It is noteworthy that half of the respondents to the larger "detransitioner" survey reported that their transition had not helped the gender dysphoria, and 70% had concluded that their gender dysphoria was related to other issues. (Vandenbussche 2021.) Without the clinical experience of monitoring the psychosocial outcomes of these young patients as they age into adulthood, many such professionals experience no challenge to their affirmative beliefs. But medical and mental health professionals who deliver trans affirmative care for those with previous and co-existing mental health problems have an ethical obligation to inform themselves, and to inform patients and parents, that these dramatic treatments are not a panacea.

199. Whether we consider physical or mental health, science does not permit us to say that either puberty blockers or cross-sex hormones are "safe," and the data concerning the mental health of patients before, during, and after such treatments strongly contradict the assertion that gender dysphoria is "easily managed."

XI. REPLY TO THE EXPERT REPORTS OF DRS. ARMAND H. MATHENY

ANTOMMARIA, DEANNA ADKINS, JACK TURBAN, AND ARON JANSSEN

A. WPATH & Endocrine Society Guidelines.

200. Section (D) of Dr. Janssen's report emphasizes how WPATH and The Endocrine Society guidelines require that trans youth undergo careful psychiatric assessment prior to starting puberty-delaying or hormonal medications. However, neither these guidelines nor Dr. Janssen provide instruction for how to perform the assessments. Instead, it is left to the individual "qualified" mental health professional—that is, mental health professionals who uncritically accept WPATH's and The Endocrine Society's standards of care. These organizations assured professionals that psychiatric, social, and learning problems did not preclude medical interventions. The frequently observed co-morbidities—autism, ADD, ADHD, learning difficulties, depression, eating disorders, anxiety states, self-harm, suicidality, and substance dependence—just had to be "under reasonable control" for a trans youth to qualify for medical interventions. This guidance, too, is not further defined. (Coleman et al., 2022). Of what value to the patient is a careful psychiatric assessment if it is not followed by a serious attempt to modify or ameliorate the observed co-morbidities? Such assessments may be useful for research purposes if instruments are designed to measure the impact of affirmative care on these co-morbidities, but this is not happening. The attempt to ameliorate the co-morbidities takes time measured in months if not longer. The downgrading of mental health treatment has led to a dramatically short duration between assessment and endocrine treatment. This was the source of the dismay of Edwards-Lepper and Anderson discussed above. (Edwards-Lepper & Anderson, 2021).

201. In 2022, WPATH removed all age requirements for the use of puberty blockers, cross-sex hormones, and mastectomies from its guidelines. In the place of age restrictions, health care providers must assess the capacity of adolescents (even 9 year-olds in the first blushes of puberty are called adolescents) to give informed consent (assent in legal terms). WPATH guidance used to

indicate that 13- and 14-years-olds were too young to undergo mastectomies; now, following the removal of age restrictions from the guidelines (Coleman et al., 2012, 2022), the operation seems justifiable for minors in their early-teen years. Patient, family, and detransitioner reports indicate that many affirmative care clinics perform brief psychiatric evaluations and fail to inquire about the influence of past processes and events on the development of a trans identity. (Levine et al., 2022). See paragraph 207 for a more recent reference to rushed care without meeting the requirement for a comprehensive psychiatric evaluation.

B. Informed Consent.

202. Neither Dr. Janssen nor Dr. Adkins question whether adolescents can provide informed consent; even more concerning, Dr. Turban's report does not even include the word "consent." They appear unaware of the longstanding international ethical unease about youthful gender dysphoria because of seven unanswered questions. One of these questions is whether these often highly psychiatric symptomatic youth are competent to make decisions about their future bodies. (Vrouenraets et al., 2015). One aspect of our recent widely read article on the subject focused on whether any adolescent has lived long enough to provide an ethical and legal informed consent for puberty blockers, cross-sex hormones, or mastectomies. (Levine et al., 2022). For purposes of affirmative care, adolescence begins at Tanner stage 2 of pubertal development, which can be attained in many children at age 9. Clinicians continue to discuss and study whether a young patient is cognitively and emotionally able to process the meaning of the social, biological, sexual, interpersonal, and psychological consequences of each step in affirmative care. (Levine, 2018; Vrouenraets et al., 2022). Forty therapists, for example, resigned from Tavistock clinic, the world's largest transgender youth clinic, because of what has been done to these children in the name of helping them. (Biggs, 2022). When thinking about this issue, it is useful for all adults concerned to recall being a child or adolescent and to consider their experience with their children's maturity at

ages 9 to 18. Judgment improves over time, and in no other arena are children and teens given responsibility to make such life changing decisions.

203. Dr. Adkins acknowledges that the Endocrine Society Guidelines require "informed consent" from patients but fails to mention how informed consent is obtained from minors. (Adkins, p. 10.) Similarly, Dr. Janssen mentions that the WPATH standards of care require clinicians to assess whether a patient has the requisite "capacity for decision-making." (Janssen, p. 12-13.) Both reports brush over the fact that legally informed consent from those under 18 must be provided by parents or guardians. Adolescents may only assent, not consent. Dr. Adkins and Dr. Janssen rely on the Endocrine Society Guidelines, which require the physician to assess the adolescent's decision-making capacity prior to prescribing puberty blockers and hormones, as if the clinician knows how to do this, and as if a 14-year-old can comprehend, let alone make a wise decision about, future sterility, sexual dysfunction, and impaired physical health.

204. Clinicians who perceive that an adolescent can give informed consent ignore an important question: does the co-existence of psychopathology limit the patient's ability to carefully think through the requested treatment? (Vrouenraets et al., 2015.) Experienced mental health professionals wonder whether adolescents' urgency for hormones or surgery—what affirmative doctors may justify as medically necessary—is a sign of the inability to consider all the necessary pros and cons of the treatments. It is imperative that clinicians understand the possible relationships between these young persons' psychopathy and gender dysphoria. Affirmative care advocates expect that their treatment will lessen the intensity of, and possibly even eradicate, the psychopathy because the depression, anxiety, social avoidance, etc. are responses to the gender dysphoria itself. Thus, we read claims of improvements after each element of affirmative care. (Note what the systematic reviews have said about this evidence.) Since the majority of adult psychiatric problems have their origins in childhood, the possibility exists that gender dysphoria is actually created in some young

people's minds as a solution to preexisting psychiatric problems. Another explanation is that psychopathology indicates inadequate coping skills for dealing with life circumstances. These poor adaptive capacities will ultimately create ongoing young adult problems despite the treatment for the gender dysphoria. Finally, the poor outcomes of post-surgical patients may be due to long standing difficulties originally unrelated to gender dysphoria. Regardless of which explanation is correct in any patient, a more reasonable approach to caring for trans-identified youth is to address therapeutically the psychiatric symptoms apart from their gender distress. I see no evidence in Dr. Adkins' or Dr. Turban's reports that they have even considered this vital topic. Possibly more concerning is the fact that Dr. Janssen nods to the concept without analyzing its implications for his opinions.

205. Parental consent for medical and surgical care rests upon the clinicians' willingness to share what is known and uncertain about the benefits and harms of treatment over time. Doctors must not mislead these concerned adults into thinking there is no alternative to affirmative care. They should not frighten them into thinking that by delaying such care they are putting their child at risk of suicide. Many affirmative care clinicians, because they don't understand the vital differences between suicidality and suicide, provide unethical coercive guidance commonly summarized as, "Would you rather have a trans daughter than a dead son?"

206. Clinicians can only inform parents and adolescents about what they themselves understand about the science. (Levine et al., 2022). The issue of informed consent often rests upon whether clinicians rely upon the previous treatment patterns—fashion-based medicine—or whether they base their thinking on evidence-based medicine.

207. International interest in the necessary components of informed consent can be seen from the reception that our March 2022 article has had. As of May 13, 2023, the paper has been downloaded across the world 61,138 times. We presume that Drs. Adkins, Turban, and Janssen have

read this paper. If they have not, one can only wonder just how aware they are about the scientific dialogue occurring on gender dysphoria. If they have read it, they have chosen to ignore it, even as clinicians all over the world have been recommending it to others at a startling pace.

208. It is my recurrent experience from case reviews, detransitioners' accounts, and communication with distressed parents and my own patients, that many of the hormone providers and surgeons rely heavily on the mental health professional's referral of the patient as the basis for the next affirmative care element. Clinicians are incorrectly assuming that medical and surgical interventions are clinically and ethically justified ("medically necessary") because a mental health professional cleared the patient for the intervention. The clinicians briefly review the possible medical or surgical complications of the intervention—hormones or surgery— they are providing. They typically do not know the mental health professional's degree, years of experience, or processes that led to the referral. The Endocrine Society's and WPATH's psychiatric evaluation policies sound substantial, but the devil is in the details of how they are carried out. (Edwards-Lepper & Anderson, 2021). In guidelines, this is described as requiring an interdisciplinary team of clinicians. Ideally, this team meets to discuss each case in depth so that the endocrinologist, the surgeon, and the MHPs share in person what is known about the patient. On February 9, 2023, such a high throughput process with minimal psychiatric evaluation at a gender clinic in Missouri was called out by a whistle blower in an affidavit, alleging multiple ethical violations. Missouri's attorney general and senator announced separate investigations.[15]

209. For years, affirmative care specialists have been promulgating their conviction that even a young child knows what gender he or she will always have. They have assured themselves that once cross-sex behavior patterns are consonant with a child's expressed interest in being a

[15] Missouri Independent (2023). *Missouri agencies launch investigation into health center for transgender youth*. https://missouriindependent.com/2023/02/09/missouri-agencies-launch-investigation-into-health-center-for-transgender-youth/.

member of the opposite sex, their current identity is fixed for life. Such ideas are clearly incorrect, but they have pervaded advocates' writings for decades.

210. Beginning on page 15 of his report, Dr. Antommaria discusses informed consent. The counter to Dr. Antommaria's assertions can be found in the paper entitled "Reconsidering Informed Consent for Trans-identified Children, Adolescents and Young Adults." (Levine et al., 2022). As noted above, it has been received with unprecedented readership throughout the world in only one year and is in the top 5% of all scientific articles published since 2012. To date, it has been downloaded approximately a thousand times per week. Our two subsequent publications are following similar patterns.

211. Affirmative Care advocates have always recognized that informed consent was legally and ethically required. The issues are the following: (1) what informed consent consists of, (2) how it is obtained, (3) what information is provided to the patient, (4) whether an ill-informed physician can conduct a legal and ethical consent process, and (5) whether a minor can consent. Contrary to Dr. Antommaria's assertions, it has not been proven that youth are mature enough to provide informed consent. One may wonder how this could be convincingly, scientifically proven. Detransitioners, who are surfacing at a new great rate, now say that they were too young to assent to treatment and could not grasp that their other psychological problems should have been discussed in psychotherapy before they assented to affirmative care. There remains considerable uncertainty among parents, patients, and mental health professionals about the cognitive maturational capacity of youth to assent. One must remember that in some settings, nine, ten, and eleven-year-olds are being treated with puberty blockers. Block has estimated that there are 18,000 children in the U.S. on these drugs. (Block 2023.) The research on the ability to consent was done by those in the forefront of affirmative care and was initiated because clinicians feel ethically uneasy about this care. There is simply no way to prove this is ethical because a passionate 14-year-old knows what will

make her happy in the future. (Vrouenraets, et al., 2020, 2021). Doctors may not be capable of leading a proper informed consent process because they do not have sufficient knowledge of the dangers of the medical treatments. If the clinician is unaware of the elevated suicide rates after gender conforming surgeries and hormonal treatment, if they are unaware of the premature mortality of adult trans persons, and if they do not recognize the multidimensional problems described by advocates within the trans communities, then they cannot help parents to consider the immediate benefits and the long terms risks involved in affirmative care. This problem may be an artifact of being a pediatric-centered professional. The study of adults may not seem that relevant to those who care for these children.

C. The Diagnosis of Gender Dysphoria

212. Dr. Antommaria and Dr. Janssen rely on the DSM-5 and DSM-5-TR (collectively "DSM") to support the assertion that gender dysphoria is a medical diagnosis. (Antommaria, p. 18; Janssen, p. 7). However, DSM contains no diagnosis of migraine headaches, thyrotoxicosis, or any other problem that has been historically labelled as medical and treated with medications and surgery. In fact, DSM contains a list of psychiatric disorders, which are patterns of dysfunction without known anatomic or fundamental physiological disruption. Treatments for these conditions target mood, thinking, or anxiety responses to living one's life with its contradictions, disappointments, and possibilities. These conditions are ideally treated by psychotherapy alone or with a combination of psychotherapy and medication.

213. Gender dysphoria is in the DSM and gender incongruence is in the ICD-11 system of classification. In the ICD-11, both sexual dysfunction and gender incongruence are in a special section called Factors Relating to Sexual Health. In the DSM, gender dysphoria is in its own section. These special sections came about for social and political reasons (Reed et al., 2016) —to aid in these patients' low self-esteem and to decrease societal discrimination. If gender dysphoria and gender

incongruence were internationally recognized to be a medical diagnosis, it would not have a presence in the DSM and would be listed in the ICD-11 section for medical illnesses.

214. In fact, the move to depathologize gender dysphoria and gender incongruence created a paradox that has been somewhat resolved by these special sections. Those who view gender dysphoria as just another aspect of human diversity are faced with the problem that medical treatments to better align the body with the mind require a diagnosis of disease for insurance coverage. Insisting these treatments are not cosmetic, advocates settled on getting insurance coverage and keeping it a psychiatric diagnosis but in a special section. This is a political compromise on the part of the advocates for medical and surgical treatments of gender dysphoria. This was the acknowledged debate when the diagnosis of gender dysphoria was retained in DSM-5.

215. Looking deeply into the vital issue of causation, all sexual behavior and sexual identities are created by an interaction of biological, psychological developmental, interpersonal, and cultural influences. Having a biological influence manifested by a child's temperament is not the same as being caused by biology. Advocates have been looking for a hypothesized biological cause in hormone profiles, brain structure, and genetic profiles. Short of finding convincing evidence, they simply declare it is biologically caused. Obviously, there is an important distinction between influenced and caused. The declaration that gender dysphoria or gender incongruence is a medical diagnosis defies its history in DSM versions since transsexualism first was classified more than a half century ago.

216. The use of puberty blockers (PB) and cross sex hormones (CSH), which of course change normal anatomy and physiology, must be ethically justified to privilege respect for patient autonomy over the primary, time-honored principle dating to 2,500 years ago: Above All Do No Harm. Four comforting but false beliefs justify calling gender dysphoria a medical diagnosis: (1) A prenatal process created GD, whenever it is expressed in the lifecycle; (2) Any trans identity is

unchangeable, immutable; (3) The incongruity between the sex of the body and one's gender identity will cause lifelong suffering if not addressed with PB, CSH, and surgery; and (4) There are no alternative treatments that can help.

217. Calling gender dysphoria a medical diagnosis is a rhetorical device to lessen the ethical concern of doing harm in the long run. Said more plainly, calling gender dysphoria a medical diagnosis is a rationalization. It makes the doctor feel better about any potential danger, such as causing sterility.

218. While patients' histories of their symptoms is inherent in all medical treatment, the point is that patients self-report their gender dysphoria and its duration, and the physician bases his or her diagnosis on that self-report. The idea that the diagnosis is based on the physician's perceptions—a qualified person making the diagnosis—is a transparent slight-of-hand for the fact that doctors have no way of ascertaining the truthfulness of the self-report. In medicine, patient history is the beginning of a process that is followed by a physical, laboratory, and radiologic examination before a diagnosis is made. With gender dysphoria, the process begins and ends with the patient's history.

D. Strength of Evidence

219. The evaluation of guidelines, such as those published by WPATH, is an esoteric skill set of those with an erudite knowledge. (Dahlen et al., 2021). Gordon Guyatt, Professor in the Department of Health Research Methods at McMasters University, is one such highly qualified evaluator. He invented the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) system. GRADE is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations. With over 100 adopting organizations worldwide, it is the most widely used tool for grading the quality of evidence. (Guyatt et al., 2008). Guyatt found serious problems with the

Endocrine Society's guidelines. He also noted that WPATH did not reveal how many systematic reviews of evidence were undertaken and what their findings were. Scientific reviews require transparency. Another reviewer of WPATH 8th version, Helfand (quoted extensively in Block, 2023), noted that there were several instances in which the strength of evidence presented to justify a recommendation was "at odds with what their own systematic reviewers found." Helfand also noted that WPATH's recommendations did not distinguish when one was based on systematic review of evidence and when it was based on consensus. (Block, 2023). Rafferty, the author of the AAP's 2018 guidance recommending social transition and affirmative care for children, and puberty blockers for older children at Tanner 2, stated that "their process doesn't quite fit the definition of a systemic review." (Block, 2023).

220. In paragraph 64 of his report, Dr. Antommaria indicates that "gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence based." Dr. Janssen makes a similar claim, citing WPATH SOC 8 in paragraph 33 of his report. Of course, the guidelines are "evidence based," but the Endocrine Society itself admits the evidence basis is of low quality—as have multiple other reviews of the evidence. (Cass, COHERE, Brignardello-Peterson & Wiercioch, and SBU). WPATH SOC 7 and 8 have been reviewed in the same low evidence basis. (Dahlen et al., 2021, Block, 2023). Moreover, all nine of the authors of the Endocrine Society's guidelines are professionals who prescribe or recommend hormones or provide surgery for trans youth. (Hembree et al., 2017). That is a far cry from the 70% standard for the GRADE field. The bias is: one finds for the procedures that one performs.

221. In paragraph 22 of his report, Dr. Antommaria states that randomized trials of individuals with gender dysphoria are, at times, "unethical." But the reason he asserts that the randomized trials are unethical is that he and others in the U.S. believe the treatments are superior to no treatment or psychotherapy. He ignores the utter lack of knowledge about the long-term outcomes

and the indicators of other adult transgender people's problems. The failure to do rigorous studies following de Vries, whose replication failed (Carmichael, 2020), is part of the problem today.

E. Low Regret Rates

222. In paragraph 56 of this report, Dr. Antommaria, like WPATH, asserts that the regret rate for adult gender-diverse patients who received affirmative care is 1.1%. He does not explain how regret is being defined to obtain this figure. (Hall et al., 2021). Regret, of course, is a common, if not universal, human experience. Transgender adolescents are not exceptions. Regret and acceptance of affirmative care can co-exist. It is not an either/or phenomenon. Regret does not preclude experiencing benefits from changing one's appearance. (Chen et al., 2023). Aesthetic benefits typically appear first. Regret's complexity can be seen in the observation that some detransitioners say that they do not have regret for having originally transitioned, but once they presented themselves as a trans person, regret eventually led to detransition. (MacKinnon, et al., 2022).

223. Though Dr. Antommaria's and Dr. Turban's reports touch on the topic of regret, they fail to adequately consider (or to consider at all) the interplay between regret and infertility secondary to gender affirming care. Transgender-identifying adolescents are generally not concerned about their future infertility. Regret is likely to appear 10 to 15 years later. Many of these teens are inexperienced with partner sex and say that they are not interested in it anyway. Later, as sexual dysfunction because of hormones, surgery, or anxiety about physical intimacy becomes a recurrent experience, regret appears. Isolation from family over time, the inability to find a stable relationship, the experience of discrimination, their need for ongoing medical care, and their coping with substance use to quell anxiety and depression—matters that they may have been warned about—begin to create waves of regret. Some eventually express regret over not having had a chance to explore their array of concerns in psychotherapy before they transitioned. (Littman, 2021).

224. Regret rates less than 1%, as quoted by Dr. Turban, defy credulity. Typical of other advocates for affirmative care, rates of regret < 2% are repeatedly quoted without discussion of how regret was defined and what percentage of the original populations were lost to follow up. These figures do not encompass patients of any age outside of medical systems who identify as trans and then return to a sex-gender compatible state. Dr. Turban's influence of external factors seems to think that external influences have no intrapsychic manifestations. This comes about because Dr. Turban does not recognize, or at least acknowledge, that trans adolescents and adults are ambivalent about their trans processes even if they are not perceived to be so by advocates.

225. There must be a hierarchy of intensity of regret related to the situations patients ultimately find themselves in. Suicide and suicide attempts must be considered as a possible manifestation of regret. After having undergone mastectomies or genital reconstruction, detransitioners rank high on the list of regret whether they consult a surgeon to see if their anatomy can be restored or an endocrinologist to administer their gonadal hormones. (Littman, 2021).

226. Lower on this hierarchy are those who recognize they are disappointed with their cross-gender lives for various reasons, whether they take steps to detransition or not. Detransitioners, and those who are resigned to making the best of their circumstances, are often angry at themselves for their naïve adolescent certainty and at their professionals' unconcerned compliance with their requests. (Littman, 2021). Lesser adaptive challenges occur to those who detransition after estrogen or testosterone has created new permanent features. (Boyd et al., 2022). Estrogen-induced larger breasts can be surgically removed, but it is not clear to what extent the long-term use of estrogen threatens sexual and testicular reproductive function. Testosterone-induced low register voices stay largely in the male range, facial hair does not disappear, and lactation is not possible when mastectomies are repaired with implants.

227. Those who detransition before taking hormones may have the least problematic new adaptations, but this too creates concerns. Years of binding may reshape breasts, for instance. Parents who objected to transition typically rejoice when an offspring detransitions. Parents who supported the transition may go through a period of embarrassment, grief, and guilt. While Dr. Antommaria's figure about regret could not possibly adequately summarize the phenomena, it does make affirmative care advocates comfortable.

XII. THE MOST RECENT SYSTEMATIC REVIEW PUBLISHED IN THE FIELD HIGHLIGHTS MANY OF THE POINTS MADE ABOVE

228. In closing this report, I would like to summarize a recently published article in detail because it highlights many of the points I have been making.

229. On April 17, 2023, a systemic review of the hormonal treatment for children with gender dysphoria was published by an eight-person team of scientists with appointments in various departments: epidemiology, pediatrics, gastroenterology, health technology, clinical science, women's and children's health, psychiatry and neurochemistry, and neuroscience and physiology. (Landen et al, 2023). It is likely that this report was one of the bases for Sweden's new national health policy, which makes psychotherapy (instead of hormonal treatment) the initial treatment approach for transgender-identified children and adolescents. Sweden now allows hormonal treatment to be only offered in research protocols. The article contains five tables, the last of which describes how future research should be conducted and reported. This table indirectly demonstrates the profound methodological problems with the current studies and gives guidance to the Karolinska Institute in Stockholm, at which future adolescents may be enrolled in protocols.

230. This project assessed psychosocial effects, bone health, body composition and metabolisms, and therapy persistence in children less than age 18 years of age who were treated with puberty blockers. The study initially identified 9,934 English language articles on the topic, but as is

usual for such processes, selected 24 studies from 2014 onward for intense scrutiny. The GRADE system, which provides four levels of evidence (very low, low, moderate, high), was used to analyze the 24 studies. Puberty blockers (PB) were typically administered to patients between 11- and 15-years-old, but the actual age range spanned from 9 to 18.6 years.

231. Six studies focused on psychosocial and mental health parameters. Global function was evaluated for 113 patients, but the certainty of the evidence "[could not] be assessed." When suicidal ideation was evaluated for 28 patients, there was no change noted and the certainty of evidence "[could not] be assessed." Similar conclusions about the certainty of evidence were found when assessing gender dysphoria, depression, anxiety, cognition, and quality of life. Each of the six studies were downgraded because of selection bias, lack of precision in measurement, absence of long-term follow-up, and inability to separate effects of the hormone from psychotherapeutic effects. One study of 20 patients on cognitive effects found no differences between the treated and untreated patients but had no pre- and post-treatment measurements. This missing method could have shown the variable effects from patient to patient — positive, negative, or no change. Mean data obscures this important information. (Landen et al, 2023).

232. The conclusion based on six longitudinal studies on bone density, only one of which was prospective, was graded "low certainty." Three studies found that before the start of PBs, bone density was lower than age mates. Bone mineralization increased less than age mate controls while on PBs, but the absolute density remained unchanged after two to three years. Even after five-plus years of cross sex hormones, the lumbar spine scores were significantly lower than before PBs were started, while other volume and femoral neck scores had normalized. A separate study of female to males on testosterone for 1-2 years failed to regain scores registered at the start of PBs. When bone geometry was studied, those treated at the onset of puberty resembled the values of their **experienced**

gender, whereas those who started PBs later in puberty remained consonant with their **biological sex**. (Landen et al, 2023).

233. Puberty blockers arrest the puberty growth spurt and lead to increased fat mass and decreased lean body mass.

234. Obesity at age 22 was more prevalent in the transgender populations.

235. From the abstract review of almost 10,000 studies, no randomized controlled studies were identified. In general, the 24 identified studies lacked control groups and intra-individual analyses, had high attrition rates (lost to follow-up or missing data), and failed to assess long term outcomes. No data were presented that dealt with those who stopped PB. The authors noted that their conclusions were consistent with the UK systemic review. The Swedish review concluded that the effects on psychosocial and somatic health are "unknown". (Landen et al, 2023).

236. Given these and similar findings from other systemic reviews free from commercial bias, such as the other recent one from McMasters University (Brignardello-Peterson & Wiercioch, 2022), it is my opinion that the terms "experimental," "unproven," or "dangerously uncertain" are justified when considering the absence of long term follow up data and the deficiencies within the current literature.

237. Given the considerable risk of harms, which include premature death (Jackson et al, 2023) and other less obvious problems discussed in this report, the question of whether minors may provide consent for medical and surgical treatments quickly arises. Others have asked, with life experiences being limited, brain development being incomplete, and psychiatric co-morbidities being present, whether any adolescent can legally give informed consent for medicalization. This is why parents are legally required to provide consent and the minor only assents. However, they cannot be expected to understand the limitations of the science pointed out by the Swedish systemic review.

My concern is that the American affirmative care clinicians and institutions that support such care also simply do not understand the limitations of science in this politicized arena.

238. When the frequently encountered psychiatric co-morbidities of trans youth are entered into consideration—autism, depression, social avoidance, anxiety states, eating disorders, suicidality, and self-harming patterns—it seems prudent not to assume that a young person has the capacity to think through the momentousness of the decision. We might expect U.S. physicians, who know the nature of scientific uncertainty, to be concerned with this haunting question of decision-making capacity, as have the Europeans. (Vrouenraets, et al, 2020.)

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct. Executed this 18th day of May, 2023.

Stephen B. Levine, M.D.

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Exhibit “A”

Brief Introduction

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the author or coauthor of numerous books on topics relating to human sexuality and related relationship and mental health issues. Dr. Levine has been teaching, providing clinical care, and writing since 1973, and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. Dr. Levine has been co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992 to the present. He received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

Personal Information

Date of birth 1/14/42

Medical license no. Ohio 35-03-0234-L

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973- Assistant Professor of Psychiatry

1979- Associate Professor

1982- Awarded tenure

1985- Full Professor

1993- Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award-1990 and 2010 (Residency program)

Visiting Professorships

- Stanford University-Pfizer Professorship program (3 days)–1995
- St. Elizabeth's Hospital, Washington, DC –1998
- St. Elizabeth's Hospital, Washington, DC--2002

Named to America's Top Doctors consecutively since 2001

Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops

Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof

2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit

2018—Albert Marquis Lifetime Achievement Award from Marquis Who's Who. (Exceling in one's field for at least twenty years)

Professional Societies

1971- American Psychiatric Association; fellow; #19909

2005- American Psychiatric Association, Distinguished Life Fellow

1973- Cleveland Psychiatric Society

1973- Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974-Society for Sex Therapy and Research

- 1987-89-President

1983- International Academy of Sex Research

1983- Harry Benjamin International Gender Dysphoria Association

- 1997-8 Chairman, Standards of Care Committee

1994- 1999 Society for Scientific Study of Sex

Community Boards

1999-2002 Case Western Reserve University Medical Alumni Association

1996-2001 Bellefaire Jewish Children's Bureau

1999-2001 Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

a. Archives of Sexual Behavior
b. Annals of Internal Medicine
c. British Journal of Obstetrics and Gynecology
d. JAMA
e. Diabetes Care
f. American Journal of Psychiatry
g. Maturitas
h. Psychosomatic Medicine
i. Sexuality and Disability
j. Journal of Nervous and Mental Diseases
k. Journal of Neuropsychiatry and Clinical Neurosciences
l. Neurology
m. Journal Sex and Marital Therapy
n. Journal Sex Education and Therapy
o. Social Behavior and Personality: an international journal (New Zealand)
p. International Journal of Psychoanalysis
q. International Journal of Transgenderism
r. Journal of Urology
s. Journal of Sexual Medicine
t. Current Psychiatry
u. International Journal of Impotence Research
v. Postgraduate medical journal
w. Academic Psychiatry

Prospectus Reviewer

a. Guilford

b. Oxford University Press

c. Brunner/Routledge

d. Routledge

Administrative Responsibilities

Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

Co-leader of case conferences at DELRLLC.com

Expert testimony at trial or by deposition within the last 4 years

Provided expert testimony for Massachusetts Dept. of Corrections in its defense of a lawsuit brought by prisoner Katheena Soneeya, including by deposition in October 2018, and in- court testimony in 2019.

Provided expert testimony by deposition and at trial in *In the Interests of the Younger Children* (Dallas, TX), 2019.

Testified in an administrative hearing in *In the matter of Rhys & Lynn Crawford* (Washington State), March 2021.

Testified multiple times in juvenile court in *In the matter of Asha Kerwin* (Tucson, Arizona), 2021.

Provided expert testimony by deposition in *Kadel et al v. Folwell et al.* (North Carolina), 2021.

Consultancies

Massachusetts Department of Corrections—evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010.

California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies.

Virginia Department of Corrections –evaluation of an inmate. New

Jersey Department of Corrections—evaluation of an inmate. Idaho

Department of Corrections—workshop 2016.

Grant Support/Research Studies

TAP–studies of Apomorphine sublingual in treatment of erectile dysfunction.

Pfizer–Sertraline for premature ejaculation.

Pfizer–Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction.

NIH- Systemic lupus erythematosis and sexuality in women.

Sihler Mental Health Foundation

a. Program for Professionals
b. Setting up of Center for Marital and Sexual Health
c. Clomipramine and Premature ejaculation
d. Follow-up study of clergy accused of sexual impropriety
e. Establishment of services for women with breast cancer

Alza–controlled study of a novel SSRI for rapid ejaculation. Pfizer–

Viagra and self-esteem.

Pfizer- double-blind placebo control studies of a compound for premature ejaculation.

Johnson & Johnson – controlled studies of Dapoxetine for rapid ejaculation.

Proctor and Gamble: multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement.

Lilly-Icos—study of Cialis for erectile dysfunction. VIVUS

– study for premenopausal women with FSAD.

Palatin Technologies- studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration.

Medtap – interview validation questionnaire studies.

HRA- quantitative debriefing study for Female partners os men with premature ejaculation, Validation of a New Distress Measure for FSD.

Boehringer-Ingelheim- double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder.

Biosante- studies of testosterone gel administration for post menopausal women with HSDD.

J&J a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.

UBC-Content validity study of an electronic FSEP-R and FSDS-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD.

National registry trial for women with HSDD.

Endoceutics—two studies of DHEA for vaginal atrophy and dryness in post menopausal women.

Palatin—study of SQ Bremelanotide for HSDD and FSAD.

Trimel- a double-blind, placebo controlled study for women with acquired female orgasmic disorder.

S1 Biopharma- a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD.

HRA – qualitative and cognitive interview study for men experiencing PE.

Publications

A) Books

1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985

2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988; Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997

3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992

4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998

5) Editor, Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.

6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003

1. 2006 SSTAR Book Award: Exceptional Merit

7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006

8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals, 2nd edition. Routledge, New York, 2010.

9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.

10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016

B) Research and Invited Papers

When his name is not listed in a citation, Dr. Levine is either the solo or the senior author.

1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73

2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26

3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2

4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974:37:9-11.

5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334

6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453

7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579

8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238

9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427

10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350

11) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5

12) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92

13) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the dysfunction? Sexual Medicine Today 1977;1:13

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